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FRIDAY, SEPTEMBER 29, 1978

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October 27 and 28, 1978

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

WHO: The Office of the Federal Register in cooperation with the Hudson Mohawk Library Association, the New York State Library, and the School of Library and Information Science at the State University of New York/Albany.

WHAT: Free public workshop (approximately 2½ hours) to present:

1. Brief history of the Federal Register system.
2. Difference between legislation and regulations.
3. Relationship of Federal Register and the Code of Federal Regulations.
4. Important elements of a typical Federal Register document.
5. An introduction to the finding aids of the FR/CFR system.

WHEN: October 27, 1978, at 1:00 p.m. and October 28, 1978 at 9:30 a.m. (Each session identical.)

WHERE: Meeting Room No. 1, Cultural Education Center, Empire State Plaza, Albany, New York.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them, as part of the General Services Administration's efforts to encourage public participation in Government actions. There will be no discussion of specific agency regulations.

RESERVATIONS: Call Elizabeth Closson, 518–474–5943.

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reminders

(The items in this list were editorially compiled as an aid to FEDERAL REGISTER users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.)

Rules Going Into Effect Today

EPA—Virginia air pollution control plans; approval of revisions 38770; 8-30-78

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Interior/FWS—Ravalli National Wildlife Refuge, Montana; migratory game bird; hunting 38010; 8-25-78

SEC—Disclosure forms and regulations amendments 34402; 8-3-78

USDA/AMS—Limes grown in Florida; order amending order 39319; 9-5-78

List of Public Laws

This is a continuing listing of public bills that have become law, the text of which is not published in the FEDERAL REGISTER. Copies of the laws in individual pamphlet form (referred to as "slip laws") may be obtained from the U.S. Government Printing Office.

[Last Listing: September 27, 1978]

S. 3075 ..... Pub. L. 95-384
International Security Assistance Act of 1978. (Sept. 26, 1978; 92 Stat. 730). Price: $.90.

S. 3119 ..... Pub. L. 95-385
To transfer certain real property of the United States to the District of Columbia Redevelopment Land Agency. (Sept. 26, 1978; 92 Stat. 749). Price: $.50.

S. 3120 ..... Pub. L. 95-386
To enhance the flexibility of contractual authority of the Temporary Commission on Financial Oversight of the District of Columbia. (Sept. 26, 1978; 92 Stat. 750). Price: $.50.

S. 1103 ..... Pub. L. 95-387
District of Columbia Reciprocal Tax Collection Act. (Sept. 27, 1978; 92 Stat. 751). Price: $.50.

S. 2556 ..... Pub. L. 95-388
To change the name of the District of Columbia Bail Agency to the District of Columbia Pretrial Services Agency. (Sept. 27, 1978, 92 Stat. 753). Price: $.50.

presidential documents

[3195-01]

Title 3—The President

Executive Order 12083 • **September 27, 1978**

Energy Coordinating Committee

By the authority vested in me as President by the Constitution of the United States of America, and in order to provide for the coordination of Federal energy policies, it is hereby ordered as follows:

1-1. *Establishment of the Committee.*

1-101. There is established an Energy Coordinating Committee, hereinafter referred to as the Committee.

1-102. The Committee shall be composed of the following, and such other members as the President may, from time to time, designate.

(a) The Secretary of Energy, who shall be the Chairman.
(b) The Secretary of State.
(c) The Secretary of the Treasury.
(d) The Secretary of Defense.
(e) The Attorney General.
(f) The Secretary of the Interior.
(g) The Secretary of Agriculture.
(h) The Secretary of Commerce.
(i) The Secretary of Labor.
(j) The Secretary of Health, Education, and Welfare.
(k) The Secretary of Housing and Urban Development.
(l) The Secretary of Transportation.
(m) The Special Representative for Trade Negotiations.
(n) The Director of the Office of Management and Budget.
(o) The Chairman of the Council of Economic Advisers.
(p) The Chairman of the Council on Environmental Quality.
(q) The Administrator of the Environmental Protection Agency.
(r) The Director of the Office of Science and Technology Policy.
(s) The Administrator of General Services.
(t) The Director of the National Science Foundation.
(u) The Assistant to the President for National Security Affairs.
(v) The Assistant to the President for Domestic Affairs and Policy.
(w) The Chairman of the Nuclear Regulatory Commission, who is invited to be a member.

1-2. *Functions of the Committee.*

1-201. The Committee shall ensure that there is communication and coordination among Executive agencies concerning energy policy and the management of energy resources.

1-202. The Committee shall, from time to time, develop and consider recommendations for improvements in the implementation of Federal energy policies or the management of energy resources that involve two or more Executive agencies.

1-203. The functions of the Committee shall neither substitute for nor replace Executive Office of the President clearance, review, and decision-making procedures. Those procedures shall also be used for submitting to the President any of the conclusions or recommendations developed through the Committee's energy coordinating functions.

1-204. The Committee shall meet at the call of the Chairman.

1-3. *Executive Council.*

1-301. During periods when the Committee is not meeting, the functions of the Committee are delegated to an Executive Council. Meetings may be called by any regular member of the Council.

1-302. The Executive Council shall be composed of the following, and such others as may be appropriate due to the specific matters to be considered.

(a) The Chairman of the Committee, who shall be Chairman of the Executive Council.

(b) The Director of the Office of Management and Budget.

(c) The Chairman of the Council of Economic Advisers.

(d) The Assistant to the President for National Security Affairs.

(e) The Assistant to the President for Domestic Affairs and Policy.

1-4. *Revocation of a Prior Order.* Executive Order No. 11814, as amended, which provided for an Energy Resources Council, is revoked.

Jimmy Carter

THE WHITE HOUSE,
September 27, 1978.

[FR Doc. 78-27687 Filed 9-27-78; 2:36 pm]

[3195-01]

Executive Order 12084 • **September 27, 1978**

Judicial Nominating Commission for the District of Puerto Rico

By the authority vested in me as President by the Constitution and statutes of the United States of America, and in order to create in accord with the Federal Advisory Committee Act (5 U.S.C. App. I) an advisory committee on judicial nominations for the District of Puerto Rico, it is hereby ordered as follows:

1-1. *Establishment of the Commission.*

1-101. There is established the Judicial Nominating Commission for the District of Puerto Rico.

1-102. The Commission shall have seven members appointed by the President. The President shall designate a Chairman from among the members.

1-2. *Functions of the Commission.*

1-201. The Commission shall begin functioning when the President or his designee notifies the Chairman that the President desires the Commission's assistance in identifying persons qualified to fill a vacancy on the United States District Court for the District of Puerto Rico.

1-202. Upon receiving such notification, the Commission shall:

(a) give public notice of the vacancy, inviting suggestions as to potential nominees;

(b) conduct inquiries to identify potential nominees;

(c) conduct inquiries to identify, among the potential nominees, persons who are well qualified to serve as a United States District Judge; and

(d) report to the President, within the time specified in the notification, the results of its activities, including a list of the persons whom the Commission considers to be best qualified to fill the vacancy.

1-203. In evaluating potential nominees, the Commission shall use standards provided by the Attorney General.

1-3. *Administrative Provisions.*

1-301. Members of the Commission shall serve without compensation. While engaged in the work of the Commission, members may receive travel expenses, including per diem in lieu of subsistence, as authorized by law (5 U.S.C. 5702 and 5703).

1-302. The Attorney General shall furnish to the Commission necessary administrative support.

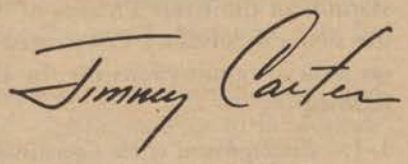
1-303. All necessary expenses incurred in connection with the work of the Commission, to the extent permitted by law, shall be paid from funds available to the Attorney General.

1-4. *General Provisions.*

1-401. A person who is a member of the Commission shall not, during the period of membership and for one year after that period, be considered by the Commission as a potential nominee.

1-402. Notwithstanding the provisions of any other Executive order, the functions of the President under the Federal Advisory Committee Act (5 U.S.C. App. I), except that of reporting annually to the Congress, which are applicable to the Commission, shall be performed by the Attorney General in accordance with the guidelines and procedures established by the Administrator of General Services.

1-403. The Commission shall terminate on December 31, 1978, unless sooner extended by the President.



THE WHITE HOUSE,
September 27, 1978.

[FR Doc. 78-27688 Filed 9-27-78; 2:37 pm]

[3195-01]

PROCLAMATION 4603

American Education Week, 1978

By the President of the United States of America

A Proclamation

Our founders assumed that an educated electorate was essential to a strong, healthy democracy. Freedom of speech, thought and inquiry are part of the basic structure of our society, and we share a fundamental belief that education can provide the key to overcoming all our problems. We have come a long way toward providing access to schools for all our people, and we provide enormous resources for education. We can be proud of that progress, as we are proud of the progress of many of our students, both youngsters and adults. But we must also recognize that many young Americans still emerge from our schools inadequately prepared to take up the responsibilities of adult life. Others have not been sufficiently challenged to develop their full potential.

Teaching has never been easy, and inspiring students is more difficult still. Perhaps it is even harder today than in the past, but it is no less crucial to the well-being of our people and of our society.

The theme of this year's American Education Week, "Education Can Turn Things Around," expresses our faith in the power of education. We expect our teachers to provide the skills, knowledge and background for understanding that will allow all Americans to make the best use of their God-given abilities. If they are to succeed, we must support these goals for human achievement in all aspects of our society. We can do this by placing our priorities and our emphasis on the lasting instead of the trivial, by rewarding quality and accomplishment, by respecting true knowledge, by raising important questions and seeking honest answers, by valuing and nurturing the capabilities of every human being.

NOW, THEREFORE, I, JIMMY CARTER, President of the United States of America, do hereby designate the week beginning November 12, 1978, as American Education Week.

It is appropriate that we honor what is right and good in education in America today—the dedicated, searching teachers who demand much of themselves and their students, who push beyond failure and discouragement to light the spark of understanding. It is appropriate, also, to recognize our responsibility as parents, grandparents, neighbors and citizens, to support the efforts of our schools to meet our high expectations, so that now and in generations to come our people may become a truly educated people.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-eighth day of September, in the year of our Lord nineteen hundred seventy-eight, and of the Independence of the United States of America the two hundred and third.

Jimmy Carter

[FR Doc. 78-27830 Filed 9-28-78; 12:12 pm]

rules and regulations

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

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

[3410-08]

Title 7—Agriculture

CHAPTER IV—FEDERAL CROP INSURANCE CORPORATION, DEPARTMENT OF AGRICULTURE

PART 417—SUGARCANE CROP INSURANCE

Subpart—Regulations for the 1979 and Succeeding Crop Years

CORRECTIONS

AGENCY: Federal Crop Insurance Corporation.

ACTION: Corrections.

SUMMARY: In FR Doc. 78-23097 appearing at pages 36423, 36424, 36425, 36426 and 36427 of the FEDERAL REGISTER of Thursday, August 17, 1978, which provided the regulations for the insuring of sugarcane with the Federal Crop Insurance Corporation, the following corrections should be noted:

FOR FURTHER INFORMATION CONTACT:

Peter Cole, 202-447-3325.

CORRECTIONS

1. In § 417.8 The Policy, subsection 1(d) appearing on page 36425 in the middle column at the top of the page, the word "plant" in the second line and the word "stubble" at the end of the third and the beginning of the fourth lines should have been italicized for emphasis.

2. In § 417.8 The Policy, subsection 3(a) appearing on page 36425 in the right column, the third line thereof should read "sugarcane crop insured shall be sugarcane," and the fourth line thereof should read "grown for processing for sugar and for."

3. In § 417.8 The Policy, subsection 3(b) appearing on page 36425 in the right column, the words "plant" in the second line and "stubble" in the third line should have been italicized for emphasis.

4. In § 417.8 The Policy, subsection 3(c) appearing on page 36425 in the right column, the first line thereof should read "(c) The Corporation reserves the right to."

5. In § 417.8 The Policy, subsection 6(d) appearing on page 36426 in the left column, the semicolon appearing in the fourth line thereof should be deleted.

6. In § 417.8 The Policy, subsection 8 appearing on page 36426 in the right column, the words "plant" in the second line and "stubble" in the third line should have been italicized for emphasis.

7. In § 417.8 The Policy, subsection 9(a) appearing on page 36426 in the right column, the tenth line from the end thereof should read "the earliest of (1) the date harvest is com-."

8. In § 417.8 The Policy, subsection 10(b) appearing on page 36426 in the right column, the semicolon in the second line thereof should be deleted, and the third line thereof should read "(1) establish the total production of sugar-."

9. In § 417.8 The Policy, subsection 10(c) appearing on page 36426 in the right column, the semicolon appearing in the third line thereof should be deleted, the fourth line thereof should read "multiplying the insured acreage of sugar-," and the word "Provided" appearing on page 36427 in the eighth line from the end thereof should have been italicized for emphasis.

10. In § 417.8 The Policy, subsection 10(d) appearing on page 36427 in the left column, the sixth line thereof should read "made by the Corporation for (1) stubble."

11. In § 417.8 The Policy, subsection 10(g) appearing on page 36427 in the left column, the word "Provided" in the sixth line thereof should have been italicized for emphasis.

12. In § 417.8 The Policy, subsection 13(a) appearing on page 36427 in the middle column, the fifth line thereof should read "for only the smaller of (1) the amount of."

13. In § 417.8 The Policy, subsection 17 appearing on page 36427 in the middle column, the seventh line thereof should read "separate records showing the same informa-."

Dated: September 27, 1978.

JOYCE M. MCCOY,
Assistant Secretary,
Federal Crop Insurance Corporation.

[FR Doc. 27613 Filed 9-28-78; 8:45 am]

[3410-05]

CHAPTER VII—AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE (AGRICULTURAL ADJUSTMENT), DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—FARM MARKETING QUOTAS AND ACREAGE ALLOTMENTS

PART 713—FEED GRAINS, UPLAND COTTON AND WHEAT

Subpart—Feed Grain, Upland Cotton and Wheat Programs for Crop Years 1978-1981

REVISION OF REGULATIONS

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Final rule.

SUMMARY: This rule sets forth the feed grain, upland cotton, and wheat program provisions for 1978-81. The authority for these programs is found in Titles IV, V, and VI of the Food and Agriculture Act of 1977. Program provisions in Parts 722 for upland cotton, 728 for wheat, and 775 for feed grains are effective only through 1977.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles J. Riley, Production Adjustment Division, Agricultural Stabilization and Conservation Service, USDA, P.O. Box 2415, Washington, D.C. 20013, 202-447-7633.

SUPPLEMENTARY INFORMATION: Because this rule merely incorporates determinations which have already been made public and since farmers are planting, cultivating, and harvesting their 1978 crop, it is hereby found and determined that compliance with the notice and public procedure provisions of 5 U.S.C. 553 is impractical and contrary to the public interest.

Similarly, due to the advanced stage of the 1978 growing season and the need for farmers to have these regulations effective upon publication, it is hereby found in accordance with the provisions of Executive Order 12044 (43 FR 12661, March 24, 1978) that it is not possible to publish these regula-

tions in proposed form and allow 60 days for public comment.

FINAL RULE

7 CFR Part 713 is added to read as follows:

Sec.
713.1 Applicability.
713.2 Administration.
713.3 Definitions.
713.4 County Yields.
713.5 Farm Yields.
713.6 Notice of normal crop acreage and yields.
713.7 Reconstitution of farms.
713.8 Requirements for program participation.
713.9 Required set-aside.
713.10 Voluntary Diversion.
713.11 Wheat grazing and hay.
713.12 Designation, use, and care of set-aside and voluntary diversion acreage.
713.13 Cross Compliance and Offsetting Compliance.
713.14 Determination of compliance.
713.15 General payment provisions.
713.16 Disaster payments.
713.17 Established (target) prices.
713.18 National program acreage.
713.19 Deficiency payments.
713.20 Division of payments and additional provisions relating to tenants and sharecroppers.
713.21 Successors-in-interest.
713.22 Misrepresentation and scheme or device.
713.23 Setoffs and assignments.
713.24 Appeals.
713.25 Performance based upon advice or action of county or State committee.

AUTHORITY: Secs. 103(f), 105A, 107A, 91 Stat. 934, 91 Stat. 928, 91 Stat. 921; (7 U.S.C. 1444, 7 U.S.C. 1445c, 7 U.S.C. 1445b).

§ 713.1 Applicability.

(a) The regulations in this subpart provide terms and conditions for the feed grain, upland cotton and wheat programs for the 1978 through 1981 crops, under which producers of feed grains, upland cotton and wheat who meet the eligibility requirements in § 713.8 may qualify for payments authorized under the programs.

In accordance with section 101 of the Agricultural Act of 1970, as amended, section 101 of the Food and Agriculture Act of 1977, and the regulations in Part 795 of this chapter, as amended, the total amount of payments (excluding disaster payments) which a person shall be entitled to receive annually under the feed grain program, the upland cotton program and the wheat program shall not exceed $40,000 in 1978, $45,000 in 1979, and $50,000 in 1980 and 1981 (including such payments under the rice program in 1980 and 1981).

(c) In accordance with the regulations in Part 796 of this chapter, as amended, payments are prohibited to program participants who harvest or knowingly permit to be harvested for illegal use marihuana or other such prohibited drug-producing plants on any part of the lands owned or controlled by them.

(d) The programs are applicable throughout the United States.

§ 713.2 Administration.

(a) The programs will be administered under the general supervision of the Administrator, Agricultural Stabilization and Conservation Service (ASCS), and shall be carried out in the field by Agricultural Stabilization and Conservation State and county committeee (herein called "State and county committees") and ASCS Management Field Office (MFO).

(b) State and county committees, MFO, and representatives and employees thereof do not have authority to modify or waive any of the provisions of the regulations in this subpart, as amended or supplemented.

(c) The State committee shall take any action required by these regulations which has not been taken by the county committee. The State committee shall also (1) correct, or require a county committee to correct, any action taken by such county committee which is not in accordance with the regulations of this subpart, or (2) require a county committee to withhold taking any action which is not in accordance with the regulations of this subpart.

(d) No delegation herein to a State or county committee shall preclude the Administrator, ASCS, or a designee, from determining any question arising under the program or from reversing or modifying any determination made by a State or county committee.

§ 713.3 Definitions.

In the regulations in this subpart and in all instructions, forms, and documents in connection therewith, the words and phrases defined in this section shall have the meaning assigned to them herein unless the content or subject matter otherwise requires. All other words and phrases shall have the meanings assigned to them in the regulations governing reconstitution of farms, Part 719 of this chapter, as amended.

(a) "Annual nonconserving crop" means any annual crop intended for harvest or utilized in any feed form, except for the following:

(1) Grasses regardless of use, including sweet sorghum, millet, and sudan grass.

(2) Legumes, other than peas or beans produced for seed, grain, or processing.

(3) Immature small grains (other than barley or wheat) destroyed by any means or used for other than grain.

(b) "Barley acreage" means:

(1) Any acreage of barley harvested for grain or planted but not harvested for grain solely because of a disaster, as determined by the county committee.

(2) Any acreage devoted to a mixture of crops if the county committee determines that the predominant crop is barley and such acreage meets the requirements of subparagraph (1) of this paragraph as being barley acreage.

(c) "Corn acreage" means:

(1) Any acreage planted to field corn or sterile high-sugar corn, excluding any acreage:

(i) Which failed and could have been replanted by the end of the corn planting period set by the State committee for the county but was not replanted.

(ii) Mechanically destroyed without feed or other benefit and not reported to ASCS as corn acreage.

(iii) Approved for a wildlife food plot in accordance with instructions issued by the Deputy Administrator.

(iv) Designated as set-aside or voluntary diversion.

(2) Any acreage devoted to a mixture of crops if the county committee determines that the predominant crop is corn and such acreage meets the requirements of subparagraph (1) of this paragraph as being corn acreage.

(d) "Crop" means the applicable crop of barley, corn, grain sorghum, upland cotton or wheat when applied to a program crop.

(e) "Cottton acreage" means any acreage planted to cotton, and any stub cotton acreage on the farm in the current year, excluding any acreage:

(i) Which failed and could have been replanted by the end of the cotton planting period set by the State committee for the county but was not replanted.

(ii) Mechanically destroyed without benefit and not reported to ASCS as cotton acreage.

(iii) Designated as set-aside or voluntary diversion.

(f) "Current year" means the calendar year in which the crop with respect to which payment may be made under this subpart would normally be harvested.

(g) "Grain sorghum acreage" means:

(1) Any acreage planted to grain sorghums of a feed grain or dual purpose variety (including any cross which, at all stages of growth, has most of the characteristics of a feed grain or dual purpose variety), excluding any acreage:

(i) Which failed and could have been replanted by the end of the grain sorghum planting period set by the State committee for the county but was not replanted.

(ii) Mechanically destroyed without feed or other benefit and not reported to ASCS as grain sorghum acreage.

(iii) Approved for a wildlife food plot in accordance with instructions issued by the Deputy Administrator.

(iv) Designated as set-aside or voluntary diversion.

(2) Any acreage devoted to a mixture of crops if the county committee determines that the predominant crop is grain sorghums and such acreage meets the requirements of subparagraph (1) of this paragraph as being grain sorghum acreage.

(h) "Marketing year" means the 12-month period beginning in the current year and ending the next year as follows:

1. *Barley and wheat.* June 1–May 31.
2. *Upland cotton.* August 1–July 31.
3. *Corn and grain sorghum.* October 1–September 30.

(i) "Rice Program" means the program authorized under title VII of the Food and Agriculture Act of 1977, part 730 of this chapter, as amended.

(j) "Wheat acreage" means:

(1) Any acreage of wheat harvested for grain or planted but not harvested for grain solely because of a disaster, as determined by the county committee.

(2) Any acreage devoted to a mixture of crops if the county committee determines that the predominant crop is wheat and such acreage meets the requirements of subparagraph (1) of this paragraph as being wheat acreage.

§ 713.4 County yields.

County yields for the current year are determined for each feed grain and wheat producing county in the United States for which the need for such yields exists. They are determined on the basis of the average yields per harvested acre for the county for the 3-year period immediately preceding the year before the current year. Adjustments are made to reflect abnormal conditions during this period. County yield data for each year are obtained from the Economics, Statistics, and Cooperatives Service, USDA. The county feed grain and wheat yields for the current year are available for inspection in the county ASCS office. County yields are not established for upland cotton.

§ 713.5 Farm yields.

(a) *Barley, corn, grain sorghum and wheat*—(1) *Determining yields.* The bushels per acre farm yield for the current year shall be the county yield for the crop, adjusted to reflect the farm productivity for the crop and established in accordance with instructions issued by the Deputy Administrator.

(2) *Provable yields.* Notwithstanding the provisions of subparagraph (1) of this paragraph, if reliable records of the actual yield in bushels per acre on the farm for each of the 3 years immediately preceding the year before the current year are available to the county committee, the yield established for the farm shall not be less than the average of such yields.

(b) *Upland cotton.* The pounds per acre farm yield for the current year shall be the average of the actual yields per harvested acre for the farm for the 3 preceding years, adjusted in accordance with instructions issued by the Deputy Administrator when the yield in any year is abnormal because of a natural disaster or other condition beyond the producer's control. If farm yield data for any year are not available or there was no production, a farm yield shall be appraised for such year on the basis of the actual yields and established yields for similar farms in the area.

(c) *Yield reduction.* For the purposes of determining eligibility for and the amount of low-yield payment as provided for in § 713.16, the established yield for the farm shall be reduced in accordance with instructions issued by the Deputy Administrator to reflect any reduction in the current year's yield which is due to causes other than a natural disaster or condition beyond the producer's control, such as a change in farming practices. Such reduced yield shall also be used for computing deficiency payments as provided for in § 713.19(c).

§ 713.6 Notice of normal crop acreage and yields.

A normal crop acreage (herein called NCA) shall be established for each farm in accordance with part 792 of this chapter, as amended, and the operator of such farm shall be notified in writing of such NCA and the yields established for the farm: *Provided,* That the notice shall not be mailed to any producer who has filed a written request that such producer not be furnished with the notice but the notice shall be filed with the producer's request in the county office. The producer may withdraw the request at any time; however, during the period a request is in effect, the producer shall be considered as having been timely and correctly notified of the contents of this notice.

§ 713.7 Reconstitution of farms.

(a) Farms shall be reconstituted in accordance with Part 719 of this chapter, as amended.

(b) The yield established for a crop for a combined farm shall not, except for rounding, exceed the weighted average of the yields established for the component parts, using the prior year's acreage of the crop for weighting. The weighted average of the yields established for the farms resulting from a division shall not, except for rounding, exceed the yield established for the parent farm prior to being divided.

§ 713.8 Requirements for program participation.

(a) *General.* A person is eligible for program benefits if such person is a producer on a farm which meets the requirements of paragraph (b) of this section and fulfills the requirements of paragraph (c) of this section.

(b) *Farm requirements.* (1) The operator of a farm on which any producer produces one or more crops for which a set-aside requirement is in effect, is participating in voluntary diversion, or is participating in wheat grazing and hay acreage for payment must do the following:

(i) File an Intention to Participate (herein called "Form 477") in accordance with instructions issued by the Deputy Administrator.

(ii) Meet set-aside requirements.

(iii) Comply with requirements in Part 792 of this chapter, as amended.

(iv) Limit the total acreage of NCA crops, required set-aside, voluntary diversion, and wheat grazing and hay acreage for payment to the farm NCA.

(2) The operator must also file, within the period authorized by the Deputy Administrator, the following:

(i) A Report of Acreage (herein called "Form 578").

(ii) A record of production and disposition when this information is needed for program determinations.

(iii) For consideration for disaster payment purposes, a Prevented Planting Claim (herein called "Form 574-1") or an Application for Disaster Credit (herein called "Form 574").

(3) Land owned by the Federal Government shall be ineligible for participation in the program if it is occupied without a lease, permit, or other right of possession.

(c) *Producer eligibility requirements.* (1) The producer must be a person who shares in the program crop produced in the current year (or the proceeds therefrom) on a farm meeting the requirements of paragraph (b) of this section, or would have shared in the crop if it had been produced on such farm in the current year, and who complies with offsetting compliance requirements provided for in Part 792 of this chapter, as amended.

(2) a minor will be eligible to participate in the program only if:

(i) The right of majority has been conferred on the minor by court proceedings.

(ii) A guardian has been appointed to manage the minor's property and the applicable documents are signed by the guardian.

(iii) A bond is furnished under which a surety guarantees to protect the Commodity Credit Corporation from any loss incurred for which the minor

would be liable had the minor been an adult. Notwithstanding the foregoing, payment may be made to a minor after December 31 of the current year upon a determination by the county committee that the minor has met the requirements of the program.

§ 713.9 Required set-aside.

(a) *1978.* The required set-aside of any crop is the following percent of the 1978 acreage of the crop, including acreage which is eligible for prevented planting credit and for which a voluntary diversion payment is approved:

(1) *Barley, corn, and grain sorghum.* 10 percent.

(2) *Upland cotton.* 0 percent.

(3) *Wheat.* 20 percent.

(b) *1979 through 1981.* to be announced by amendment to this subpart.

§ 713.10 Voluntary diversion.

(a) *1978.* (1) In order to be eligible for a voluntary diversion payment, the farm operator may elect to divert an acreage of cropland for voluntary diversion payment for any or all of the crops of barley, corn, grain sorghum, and upland cotton. Such diversion shall be equal to 10 percent of the sum of the 1978 acreage of the crop and any acreage which is eligible for prevented planting credit as determined by the county committee. This acreage for 1978 may not exceed the 1977 planted acreage of the crop (1976 planted acreage for farms with odd-even rotations), less, in the case of upland cotton, the upland cotton voluntary diversion. Voluntary diversion does not apply to wheat.

(2) The intention to participate in voluntary diversion must be recorded on Form 477, "Intention to Participate." Payment will be for all crops actually planted for harvest which meet voluntary diversion requirements.

(3) The diversion payment shall be $0.20 for corn, $0.12 for barley and grain sorghum, and $0.02 for upland cotton times the yield established for the crop as provided for in § 713.5 and times the sum of the 1978 acreage of the crop and the acreage eligible for prevented planting credit as determined by the county committee.

(4) Producers may elect to receive one-half of the diversion payment when Form 477 is filed, based upon the acreage intended to be planted to the crop.

(5) Diversion payments made to any producer which exceed the total diversion payments the producer earns under the programs with respect to any farm shall be refunded to the Commodity Credit Corporation (CCC). If for any reason such earned payments are zero, the producer shall pay interest at the rate of 7 percent per annum on the amount of the refund from the date of issuance of the CCC sight drafts to the date such payments are refunded. The provisions of the foregoing sentence requiring the payment of interest when no payment is earned shall not apply if the producer receives an unearned payment through no fault of the producer.

(b) *1979 through 1981.* To be announced by amendment to this subpart.

§ 713.11 Wheat grazing and hay.

(a) *1978.* (1) In order to be eligible for a wheat grazing and hay payment, the farm operator may elect to graze or cut immature wheat for (i) green chop, (ii) hay, or (iii) silage if the wheat was planted for harvest as grain. The wheat acreage intended for grazing and hay payment must be recorded on Form 477. No set-aside is required for this acreage.

(2) The acreage eligible for payment is limited to the larger of 50 acres or 40 percent of the total acreage of barley, corn, grain sorghum, upland cotton, and wheat which is intended for harvest in 1978, but not in excess of the NCA.

(3) Payment shall be the higher of the 1978 wheat deficiency rate per bushel or $0.50 times the yield established as provided for in § 713.5 times the wheat acreage eligible for grazing and hay payment. Such payment shall not be made on more acreage than that actually used for this purpose.

(4) Producers may receive one-half of the wheat grazing and hay payment when Form 477 is filed, based on $0.50 per bushel.

(5) Wheat grazing and hay payments made to any producer which exceed the total wheat grazing and hay payment the producer earns for the farm shall be refunded to CCC. If for any reason such earned payment is zero, the producer shall pay interest at the rate of 7 percent per annum on the amount of the refund from the date of issuance of the CCC sight drafts to the date such payments are refunded. The provisions of the foregoing sentence requiring the payment of interest when no payment is earned shall not apply if the producer receives an unearned payment through no fault of the producer.

(b) *1979 through 1981.* To be announced by amendment to this subpart.

§ 713.12 Designation, use, and care of set-aside and voluntary diversion acreage.

The regulations governing the designation, use, and care of set-aside and voluntary diversion acreage are set forth in Part 792 of this chapter, as amended.

§ 713.13 Cross compliance and offsetting compliance.

The regulations governing cross compliance on the farm and offsetting compliance between farms are set forth in Part 792 of this chapter, as amended.

§ 713.14 Determination of compliance.

(a) Acreage determinations shall be made in accordance with Part 718 of this chapter, as amended.

(b) A representative of the State or county committee or any authorized representative of the Secretary shall have the right at any reasonable time to enter a farm concerning which representations have been made on any forms filed under a program. Such entry may be for any of the following purposes:

(1) To measure acreage.

(2) To examine any records pertaining to the program.

(3) To determine otherwise the accuracy of a producer's representations and the performance of his obligations under the program.

§ 713.15 General payment provisions.

(a) *Issuance.* Payments of any amounts due the producers on a farm shall be made only after they sign an application for payment as prescribed by the Deputy Administrator and the payments are approved by the county committee or by an authorized representative thereof. An application for payment which is signed after May 1 of the year following the current year shall not be accepted by the county committee unless prior approval of the State committee is obtained.

(b) *Failure to comply fully.* Except as otherwise provided herein and in Part 791 of this chapter, as amended, payment shall not be made for a farm or to a producer when there is failure to comply fully with the regulations contained in this subpart, and in Part 718 of this chapter, as amended.

(c) *Payment due producer.* Subject to the provisions of the payment limitation regulations in Part 795 of this chapter, as amended, the total earned payment due each eligible producer under the program shall be determined by multiplying the total earned payment for the farm by the producer's share of such payment.

(d) *Payment declined.* If a producer declines to accept all or any part of his share of the payment computed for a farm in accordance with the provisions of this section, such payment or portions thereof shall not become available for any other producer on the farm.

(e) *Unearned payments.* Deficiency and disaster payments made to any producer which exceed the total deficiency and disaster payments the producer earns under the program with

respect to any farm shall be refunded to CCC. If for any reason such earned payments are zero, the producer shall pay interest at the rate of 7 percent per annum on the amount of refund from the date of issuance of the CCC sight drafts to the date such payments are refunded. The provisions of the foregoing sentence requiring the payment of interest when no payment is earned shall not apply if the producer earns any rice deficiency or disaster payments for the farm or receives an unearned payment through no fault of the producer.

§ 713.16 Disaster payments.

Prevented planting and low yield disaster payments are authorized only for 1978 and 1979. Producers may qualify for disaster payments only when the county committee determines that prevented planting or a low yield as hereinafter described in this section occurs because of a natural disaster or other condition beyond the producer's control. Disaster payments shall be made as soon as practicable after the disaster is reported, the extent of the crop loss is determined, and payment is approved.

(a) *Prevented planting.*—(1) *Payment rate.* The prevented planting payment rate is one-third of the established price as provided for in § 713.17.

(2) *Acreage eligible for payment.* The acreage eligible for payment shall equal the smaller of:

(i) The acreage of the crop intended for harvest within program requirements but which could not be planted to the crop or other annual nonconserving crops because of a natural disaster or other condition beyond the producer's control, or

(ii) The amount by which the prior year's acreage of the crop (the acreage for the year before the prior year for farms with odd-even rotations) plus the acreage approved for prevented planting payment in such year exceeds the current year's acreage of the crop.

(3) *Payment computation.* Prevented planting payments shall be determined for each crop by multiplying the acreage for payment by 75 percent of the established farm yield as provided for in § 713.5 and by the prevented planted payment rate.

(b) *Low yield.*—(1) *Payment rate.* The low-yield payment rate is one-third for upland cotton and one-half for barley, corn, grain sorghum, and wheat of the established price as provided for in § 713.17.

(2) *Acreage for payment.* The acreage for payment shall be the current year acreage of the crop.

(3) *Payment Computation.* Low-yield payments shall be determined for each crop by multiplying the acreage for payment by 60 percent (75 percent for upland cotton) of the established farm yield as provided for in § 713.5, subtracting the determined production therefrom, and multiplying the result by the low-yield payment rate.

(i) The production from acreage not harvested shall be appraised and added to the actual production for the purpose of determining the eligibility for the amount of low-yield payments, in accordance with instructions issued by the Deputy Administrator.

(ii) Any acreage for which the production cannot be determined shall be charged with the established yield: *Provided,* That if the county committee determines that the acreage was affected by a disaster, the acreage shall be charged with the larger of 60 percent (75 percent for upland cotton) of the established farm yield as provided for in § 713.5 or the actual average yield from the harvested acreage of the crop.

§ 713.17 Established (target) prices.

(a) *1978.* Established prices are set as follows:

(1) *Barley.* $2.25 per bushel.
(2) *Corn.* $2.10 per bushel.
(3) *Grain Sorghum.* $2.28 per bushel.
(4) *Upland Cotton.* $.52 per pound.
(5) *Wheat.* $3.40 per bushel.

(b) *1979 thru 1981.* To be announced by amendment to this subpart.

§ 713.18 National program acreage.

A national program acreage shall be established for each crop equal to the number of harvested acres the Secretary of Agriculture estimates will produce the quantity (less imports) that will be utilized domestically and for export during the marketing year for such crop. Established national program acreages may later be revised for the purpose of determining an allocation factor for use as provided for in § 713.19(b) if the Secretary of Agriculture determines that an adjustment is necessary based upon the latest information.

(a) *1978.* National program acreages are established as follows:

(1) *Barley.* 7,400,000 acres.
(2) *Corn.* 67,600,000 acres.
(3) *Grain Sorghum.* 13,700,000 acres.
(4) *Upland Cotton.* 10,248,000 acres.
(5) *Wheat.* 58,700,000 acres.

(b) *1979 thru 1981.* To be announced by amendment to this subpart.

§ 713.19 Deficiency payments.

(a) *Payment rate.* The deficiency payment rate shall be the amount by which the established price exceeds the higher of (1) the national weighted average market price received by farmers for the crop during the first 5 months of the marketing year (during the current year for upland cotton) or (2) the national average loan rate established for the crop.

(b) *Acreage for payment.* The acreage for payment shall be the current year acreage of the crop reduced by an allocation factor, when less than 100 percent, determined by dividing the national program acreage established for the crop by the estimated national current year acreage of the crop: *Provided,* That (1) the allocation factor shall not be less than 80 percent for barley, corn, grain sorghum, and wheat.

(2) the acreage for payment shall not be reduced by the allocation factor if the current year acreage of the crop on the farm is reduced voluntarily by the producer from the sum of the prior year's acreage (the acreage for the year before the prior year for farms with odd-even rotations) and the acreage credited for such year by the county commmittee for underplanting, prevented planting, set-aside, voluntary diversion, and grazing and hay for payment by the following percent:

(i) *1978.*

(A) *Barley, upland cotton, and wheat.* 20 percent.

(B) *Corn and grain sorghum.* 5 percent.

(ii) *1979 thru 1981.* To be announced by amendment to this subpart; and (3) the allocation factor shall be adjusted in accordance with instructions issued by the Deputy Administrator to provide equity for a farm for which the reduction in current year's acreage of the crop from the prior year acreage (the acreage for the year before the prior year for farms with odd-even rotation) is insufficient to exempt the farm from the application of the allocation factor.

(c) *Payment computation.* Deficiency payments shall be determined for each crop by multiplying the acreage for payment by the established farm yield as provided for in § 713.5 and by the deficiency payment rate: *Provided,* That no deficiency payment shall be made for any quantity for which a low yield payment is made.

(d) *Date of payment.* Deficiency payments will be made to producers as soon as practicable after the following dates:

(1) *Barley and wheat.* December 1.
(2) *Upland Cotton.* February 1 following the current year.
(3) *Corn and grain sorghum.* April 1 following the current year.

§ 713.20 Divison of payments and additional provisions relating to tenants and sharecroppers.

The regulations relating to the division of payments and additional provisions relating to tenants and sharecroppers are set forth in Part 794 of this chapter, as amended.

§ 713.21 Successors-in-interest.

(a) In the case of death, incompetency, or disappearance of any producer whose name appears on the application for payment, the payment due such producer shall be made to such producer's successor, as determined in accordance with the regulations in Part 707 of this chapter, as amended.

(b) When any person who had an interest as a producer of the crop or would have had an interest as a producer if the crop had been planted (herein called "predecessor") is succeeded on the farm by another producer (herein called "successor") after an application for payment has been filed, the payment to the predecessor and successor shall be divided between them on such basis as they agree is fair and equitable. If such persons are unable to agree to a division of the payment, a fair and equitable division shall be determined by the county committee.

(c) In any case where any payment due any successor producer has previously been paid to the producer who filed an application for payment, such payment shall not be paid to the successor producer unless it is recovered from the producer to whom it has been paid or payment is authorized by the Deputy Administrator.

§ 713.22 Misrepresentation and scheme or device.

(a) A producer who is determined by the county committee or the State committee to have erroneously represented any fact affecting a program determination shall not be entitled to payments under the program for the farm with respect to which the representation was made and shall refund to the Commodity Credit Corporation the payments received by such producer with respect to such farm.

(b) A producer who is determined by the State committee, or the county committee with the approval of the State committee, to have knowingly (1) adopted any scheme or device which tends to defeat the purpose of the program, (2) made any fraudulent representation, or (3) misrepresented any fact affecting a program determination shall refund to the Commodity Credit Corporation all payments received by such producer with respect to the program.

(c) The provisions of this section shall be applicable in addition to any liability under criminal and civil fraud statutes.

§ 713.23 Setoffs and assignments.

(a) *Producer indebtedness.* The regulations issued by the Secretary governing setoffs, and withholdings, Part 13 of this chapter, as amended, shall be applicable to the programs.

(b) *Assignments*—(1) *Barley, corn, grain sorghum, and wheat.* Payments may be assigned only to the Farmers Home Administration in accordance with instructions issued by the Deputy Administrator.

(2) *Upland cotton.* Any producer entitled to any payment may assign his rights thereto in accordance with the regulations governing assignment of payment, Part 709 of this chapter, as amended.

§ 713.24 Appeals.

A producer may obtain reconsideration and review the determinations made under this subpart in accordance with the Appeal Regulations, Part 780 of this chapter, as amended.

§ 713.25 Performance based upon advice or action of county or State committee.

The provisions of Part 790 of this chapter, as amended, relating to performance based upon action or advice of an authorized representative of the Secretary shall be applicable to this subpart.

NOTE.—An approved final Impact Analysis Statement is available from Bruce R. Weber, Production Adjustment Division, Agricultural Stabilization and Conservation Service, USDA, P.O. Box 2415, Washington, D.C. 20013, 202-447-7987.

Signed at Washington, D.C., on September 20, 1978.

RAY FITZGERALD,
Administrator.

[FR Doc. 78-27107 Filed 9-28-78; 8:45 am]

[3410-02]

CHAPTER X—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; MILK), DEPARTMENT OF AGRICULTURE

[Docket No. A0-231-A46]

PART 1126—MILK IN THE TEXAS MARKETING AREA

Order Amending Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action provides for changes in the present order provisions based on industry proposals considered at a public hearing held June 13-14, 1978. The amendments would relax the "dairy farmer for other markets" provision and would modify the provisions relating to diversions of milk to nonpool plants. These provisions are used to determine which dairy farmers are eligible to have their milk pooled and priced under the Federal order. The amendments are necessary to reflect current marketing conditions and to insure orderly marketing in the area.

EFFECTIVE DATE: October 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, D.C. 20250, 202-447-4824.

SUPPLEMENTARY INFORMATION: Prior documents in this proceeding:

Notice of hearing: Issued May 26, 1978, published June 1, 1978 (43 FR 23725).

Partial recommended decision: Issued August 4, 1978, published August 8, 1978 (43 FR 35047).

Final decision: Issued September 1, 1978, published September 8, 1978 (43 FR 40030).

FINDINGS AND DETERMINATIONS

The findings and determinations set forth below are supplementary and in addition to the findings and determinations previously made in connection with the issuance of the Texas order and of the previously issued amendments to it. All of the previous findings and determinations are hereby ratified and affirmed, except insofar as such findings and determinations may be in conflict with the findings and determinations set forth herein.

(a) *Findings.* A public hearing was held upon certain proposed amendments to the tentative marketing agreement and to the order regulating the handling of milk in the Texas marketing area. The hearing was held pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 et seq.), 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 order[1] 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 said marketing area, and the minimum prices specified in the order as hereby amended, are such prices as will reflect the aforesaid factors, insure a sufficient

[1] 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.

quantity of pure and wholesome milk, and be in the public interest; and

(3) The said order as hereby amended, regulates the handling of milk in the same manner as, and is applicable only to persons in the respective classes of industrial or commercial activity specified in, a marketing agreement upon which a hearing has been held.

(b) *Additional findings.* It is necessary in the public interest to make this order amending the order effective not later than October 1, 1978. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing area.

The provisions of this order are known to handlers. The recommended decision of the Deputy Administrator, Regulatory Programs, was issued August 4, 1978, and the decision of the Assistant Secretary containing all amendment provisions of this order was issued September 1, 1978. The changes effected by this order will not require extensive preparation or substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that good cause exists for making this order amending the order effective October 1, 1978, and that it would be contrary to the public interest to delay the effective date of this amendment for 30 days after its publication in the FEDERAL REGISTER. (Sec. 553(d), Administrative Procedure Act, 5 U.S.C. 551-559.)

(c) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in section 8c(9) of the Act) of more than 50 percent of the milk marketed within the marketing area to sign a proposed marketing agreement tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of this order amending the order is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the order as hereby amended; and

(3) The issuance of this amended order is approved or favored by at least two-thirds of the producers who participated in a referendum and who during the determined representative period were engaged in the production of milk for sale in the marketing area.

ORDER RELATIVE TO HANDLING

It is therefore ordered, That on and after the effective date hereof, the handling of milk in the Texas marketing area shall be in conformity to and in compliance with the terms and conditions of the aforesaid order, as amended, and as hereby further amended, as follows:

1. Section 1126.12(b)(5) is revised as follows:

§ 1126.12 **Producer.**

* * * * *

(b) * * *

(5) Any person with respect to milk produced by him during the months of February through July that is caused to be delivered to a pool plant by a cooperative association or a pool plant operator if during any of the immediately preceding months of September through November more than one-third of the milk from the same farm was caused by such cooperative association or pool plant operator to be delivered to plants as other than producer milk (except milk that is not producer milk as a result of a temporary loss of grade A approval or the application of § 1126.13(e) (4) and (5)), unless such pool plant was a nonpool plant during any of such immediately preceding months.

2. In § 1126.13, the introductory text of paragraph (e) immediately preceding subparagraph (1), and paragraph (e)(1) are revised as follows:

§ 1126.13 **Producer milk.**

* * * * *

(e) Diverted from a pool plant to a nonpool plant that is not a producer-handler plant for the account of the handler operating such pool plant or a handler described in § 1126.9(b), subject to the following conditions:

(1) Milk of a dairy farmer shall not be eligible for diversion during any month unless milk of such dairy farmer was physically received as producer milk at a pool plant and the dairy farmer has continuously retained producer status since that time and further, during each of the months of September through January not less than 15 percent of the milk of such dairy farmer is physically received as producer milk at a pool plant. If a dairy farmer loses his producer status under the order (except as a result of a temporary loss of Grade A approval), his milk shall not be eligible for diversion until milk of such dairy farmer has been physically received as producer milk at a pool plant;

* * * * *

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

Effective date: October 1, 1978.

Signed at Washington, D.C., on September 26, 1978.

JERRY C. HILL,
Deputy Assistant Secretary.

[FR Doc. 78-27640 Filed 9-28-78; 8:45 am]

[3410-02]

CHAPTER IX—AGRICULTURAL MARKETING SERVICE (MARKETING AGREEMENTS AND ORDERS; FRUITS, VEGETABLES, NUTS), DEPARTMENT OF AGRICULTURE;

[Lemon Reg. 166]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This regulation establishes the quantity of fresh California-Arizona lemons that may be shipped to market during the period October 1-7, 1978. Such action is needed to provide for orderly marketing of fresh lemons for this period due to the marketing situation confronting the lemon industry.

EFFECTIVE DATE: October 1, 1978.

FOR FURTHER INFORMATION CONTACT: Charles R. Brader, 202-447-6393.

SUPPLEMENTARY INFORMATION: *Findings.* Pursuant to the marketing agreement, as amended, and Order No. 910, as amended (7 CFR Part 910), regulating the handling of lemons grown in California and Arizona, effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), and upon the basis of the recommendations and information submitted by the Lemon Administrative Committee, and upon other information, it is found that the limitation of handling of lemons, as hereafter provided, will tend to effectuate the declared policy of the act.

The committee met on September 26, 1978, to consider supply and market conditions and other factors affecting the need for regulation and recommended a quantity of lemons deemed advisable to be handled during the specified week. The committee reports the demand for lemons remains good for sizes 140's and larger, but weaker on 165's and smaller.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the FEDERAL REG-

ISTER (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation is based and the effective date necessary to effectuate the declared policy of the act. Interested persons were given an opportunity to submit information and views on the regulation at an open meeting. It is necessary to effectuate the declared purposes of the act to make these regulatory provisions effective as specified, and handlers have been apprised of such provisions and the effective time.

§ 910.466 Lemon regulation 166.

Order. (a) The quantity of lemons grown in California and Arizon which may be handled during the period October 1, 1978, through October 7, 1978, is established at 225,000 cartons.

(b) As used in this section, "handled" and "carton(s)" mean the same as defined in the marketing order.

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

Dated: September 27, 1978.

CHARLES R. BRADER,
Acting Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 78-27791 Filed 9-27-78; 8:45 am]

[3410-07]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS AND GRANTS PRIMARILY FOR REAL ESTATE PURPOSES

[FmHA Instruction 444.5]

PART 1822—RURAL HOUSING LOANS AND GRANTS

Subpart D—Rural Rental Housing Loan Policies, Procedures, and Authorizations

Amendment and Deletion

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration amends its regulations regarding rural rental housing. This action is taken as a result of an administrative decision. The intended effect of this action is to simplify the regulations by issuing Agency forms to replace five exhibits in the present regulations and to eliminate the rider in the rental assistance agreement by use of the modified agreement.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Paul Conn, Director, Multiple Family Housing Loan Division, 202-447-7207.

SUPPLEMENTARY INFORMATION: Exihibits J-2, R-1, R-2, R-3, and R-4 of subpart D, part 1822, Chapter XVIII, Title 7 in the Code of Federal Regulations are deleted and appropriate cross references are corrected. These exihibits were only used as a temporary measure until the approved forms were available. The forms are available for inspection at FmHA County Offices. It is the policy of this Department that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. These deletions and amendments, however, are not published for proposed rulemaking since the purpose of the deletion is administrative in nature and does not affect the substance of the regulation.

Accordingly, Subpart D of Part 1822 is amended as follows:

1. In the Table of Contents, delete entries for exhibits J-2, R-1, R-2, R-3, and R-4.

2. Paragraph IV. B. 2. e. of exhibit J of subpart D is amended to read as follows:

EXHIBIT J—INTEREST CREDITS ON INSURED RRH AND RCH LOANS

* * * * *

IV. *Options of borrowers:*

* * * * *

B. *Plan II.*

* * * * *

2. * * *

* * * * *

e. Determine the required monthly payment on the loan at 1 percent interest and overage each month for the total units developed with any one loan. The amount of payment will be computed separately for each loan using form FmHA 444-29, "Project Worksheet for Multiple Family Housing Projects."

* * * * *

3. Exhibit J-2, "Project Worksheet For Multiple Family Housing Projects," is hereby deleted and reserved.

4. Paragraphs V A 1, C 2, IX B 1 and 2, X A 1, C 1, 2, 3, and 4, XI and XIII of exhibit R to subpart D are amended to read as follows:

EXHIBIT R—RENTAL ASSISTANCE PROGRAM

* * * * *

V. *Priority of Rental Assistance Applications.* * * *

A. * * *

1. *Existing Housing:* The State Director will distribute any units allocated to the State for existing RRH, RCH, and LH projects by considering all forms FmHA 444-25, "Request for Rental Assistance," that have been submitted by eligible borrowers. The State Director shall authorize rental assistance to projects with priority given to projects based on the earliest date that form FmHA 444-25 and other required information is submitted to FmHA in acceptable form (see paragraph X). The number of units to be granted in any project will be based on the number of tenants in the project needing rental assistance up to the maximum allowed. The National Office shall notify the State Director each year of any specific date by which all requests for rental assistance must be submitted to FmHA for consideration.

* * * * *

C. *Processing Exception Requests.* * * *

2. The State Director will maintain form FmHA 444-28, "Record of Rental Assistance Agreement." The record will include the borrower's case number, fund code, loan number, number of units in the project, number of units for rental assistance authorized and the effective date of each agreement and amendment. This information will be obtained from form FmHA 444-25, "Request for Rental Assistance Agreement," form FmHA 444-26, "Request for Obligation of Rental Assistance," and form FmHA 444-27, "Rental Assistance Agreement." Any changes which are made in the number of rental units assisted will be recorded in the Record of Rental Assistance Agreements. Form FmHA 444-28 will be used for keeping this record.

* * * * *

IX. *Terms of the Rental Assistance Agreement.*

* * * * *

B. *Term.*

1. *For New Construction.* The term of the agreement shall be for a period of twenty (20) years from the effective date of the agreement unless superseded by a modified agreement in accordance with section 4 of the Rental Assistance Agreement or terminated in accordance with conditions stated in section 8 or section 10 of the Rental Assistance Agreement. Modified agreements will extend only for the remaining period of the original agreement. (A new construction project is one in which no unit has been occupied.) Upon expiration of the twenty year period, a new agreement may be executed. If a new agreement is considered, it will be made for a period not to exceed five (5) years.

2. *For Existing Construction.* The term of the agreement shall be for a period of five

(5) years from the effective date of the agreement unless superceded by a modified agreement in accordance with section 4 of the Rental Assistance Agreement or terminated in accordance with conditions stated in section 4 or section 10 of the Rental Assistance Agreement. Modified agreements will extend only for the remaining period of the original agreement. (An existing project is one in which one or more units have been occupied.) Prior to the termination date of any agreement a new form FmHA 444-25, "Request for Rental Assistance," may be submitted. If a new agreement is consummated, it will be made for a period not to exceed five (5) years.

* * * * *

X. *Processing of Rental Assistance Applications.* * * *

A. * * *

1. A borrower with an eligible project in which there are tenants paying in excess of 25 percent of their adjusted income for rent is encouraged to file form FmHA 444-25, "Request for Rental Assistance," with the County Supervisor. A separate form FmHA 444-25 will be submitted for each project. The borrower should include the following with each request.

a. Form FmHA 444-29, "Project Worksheet for Interest Credit and Rental Assistance" with columns 1 through 12 completed for each tenant in the project.

* * * * *

C. *State Director Action on Requests for Rental Assistance.*

1. If the State Director determines that rental assistance can be granted, or a change in the number of units is needed, form FmHA 444-26, "Request for Obligation of Rental Assistance," will be prepared. Form FmHA 444-26 will be prepared and distributed in accordance with the forms Manual Insert. *The form FmHA 444-27, "Rental Assistance Agreement," will not be executed until the Request for Obligation of Rental Assistance has been returned from the Finance Office indicating that the requested number of units and funds have been obligated for the project.*

2. *Initial requests.* Once the initial request for rental assistance has been obligated by the Finance Office, the State Director will prepare an original and three copies of form FmHA 444-7, "Interest Credit and Rental Assistance Agreement," and an original and two copies of form FmHA 444-27. The State Director will keep one copy of the forms in the State Office borrower file. The original and two copies of form FmHA 444-7 and the original and one copy of form FmHA 444-27 will be sent to the County Office with a covering memorandum authorizing the County Supervisor to execute the agreements. Both originals and copies will be executed by the borrower and County Supervisor. The County Supervisor will retain the original of form FmHA 444-27 in the borrower file and the executed copy will be given to the borrower. The County Supervisor will send the original of form FmHA 444-7 to the Finance Office, retain a copy in the borrower's file and an executed copy will be given to the borrower.

3. *Modification of an existing agreement.* When a change in the number of rental assistance has been obligated by the Finance Office the form FmHA 444-27 will be prepared, signed and distributed in the same manner as provided for in paragraph X C 2 except a form FmHA 444-7 is not required.

4. If rental assistance cannot be provided, the State Director will, by letter, through the County Supervisor, inform the borrower in writing of the reasons.

* * * * *

XI. *Method of Payment of Rental Assistance to Borrower.* The borrower will prepare a separate report for the project using form FmHA 444-29. The worksheet will be prepared and distributed in accordance with the instructions for preparation or the forms Manual Insert. This information will be used by County Supervisor in preparation of form FmHA 444-9, "Multiple housing Certification and Payment Transmittal." The form must be completed in accordance with the FMI. The required payment will be transmitted with the form to the Finance Office. The rental assistance payment will be mailed by the Finance Office directly to the borrower within 15 working days of receipt of a properly completed form FmHA 444-9. Since the check will be sent directly to the borrower, the County Supervisor must be sure that the borrower's address on form FmHA 440-57, "Acknowledgement of Obligated Funds/Check Request," and 450-14, "Annual Statement of Loan Account," are correct. If the address shown on these forms is not correct, the County Supervisor will complete form FmHA 450-10, "Advise of Borrower's Change of Address or Name," prior to any request for payment of rental assistance. However, when a borrower has more than one project within a county, all checks must be sent to the same address.

* * * * *

XIII. *Forms and Exhibits.* Incorporated as a part of this regulation are Exhibit F-5A and Form FmHA 444-7.

5. Exhibits R-1, R-2, R-3, and R-4 are deleted.

(42 U.S.C. 1480; delegation of authority by the Secretary of Agriculture, 7 CFR 2.23; delegation of authority by the Assistant Secretary for Rural Development, 7 CFR 2.70.)

Dated: September 27, 1978.

JAMES E. THORNTON
Associate Administrator
Farmers Home Administration.

[FR Doc. 78-27800 Filed 9-28-78; 8:45 am]

[7590-01]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 20—STANDARDS FOR PROTECTION AGAINST RADIATION

Personnel Monitoring Reports

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission is amending its regulations to extend to all NRC specific licensees the requirement for submission of an annual statistical summary report on radiation exposure of workers. The existing requirement applies only to four categories of licensees that were considered to involve the greatest potential for significant occupational exposures, i.e., nuclear power reactors, industrial radiographers, nuclear fuel processors and reprocessors, and certain large commercial suppliers of byproduct materials. The amendments do not involve any changes in the requirements for the provision and use of personnel monitoring equipment or the records of personnel monitoring data that must be kept by licensees. The changes relate solely to reporting data already being recorded. The regulation requiring certain reports on termination of employment or work assignment in the facilities of the four categories of licensees is being amended only to change the recipient of the reports and to specify the same four categories of licensees.

Those categories are currently set out in another section and incorporated by reference in the section requiring termination reports.

EFFECTIVE DATE: December 13, 1978.

NOTE.—The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for such reviews as may be appropriate under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the reporting requirement of this rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for such review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Mr. Walter S. Cool, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 telephone 301-443-5970.

SUPPLEMENTARY INFORMATION: On May 30, 1975, the Nuclear Regulatory Commission (NRC) published in the FEDERAL REGISTER (40 FR 23478), a notice of proposed amendments to 10 CFR Part 20 that would extend to all NRC specific licensees the requirements of § 20.407 for the submission of an annual statistical summary report of estimated whole body radiation doses. Section 20.408 would be amended only to specify the same four categories of licensees presently required to submit reports of individual exposure to radiation and radioactive material upon termination of employment or work assignment in their facilities. Those categories are currently set out in § 20.407(a) and incorporated in § 20.408 by reference.

By letter dated June 2, 1975, copies of the notice of proposed rulemaking were sent to all specific licensees. A majority of the 36 comments submitted in response to the notice of proposed rulemaking favored the amendments, but offered some suggestions for change. Many of the commenters who opposed the proposed amendments were medical licensees who expressed opposition to the filing of any additional reports. They noted that additional paperwork increases cost of health care delivery, and hence is inflationary. Opinions were expressed that the proposal might have theoretical value, but would not be practical, that insufficient need has been shown for another administrative requirement with low benefit/cost ratio, that occupational exposures (in medical diagnosis and therapy) are "as low as practicable", that the existing requirement (§ 20.403) for reporting overexposures is quite adequate to make licensees aware of their responsibilities in cases of overexposure and only licensees with repeated overexposures should be asked to submit annual statistical summary reports, that it is not possible to separate exposures received while working with NRC-licensed material from exposures received while working with X-ray, radium, or other radiation sources not subject to NRC regulations, and that there are inherent inaccuracies in personnel monitoring data. One commenter suggested that NRC send each licensee (1) a summary of the data collected, and (2) a reminder of the reporting requirement and a form suitable for recording the data. One commenter indicated a need for a longer time period in which to prepare the report. Some commenters misunderstood the proposed amendment to § 20.408, believing that it would extend to all licensees the requirement for reports of individual exposures upon termination of employment with a licensee or work assignment in the licensee's facility.

In view of the comments that raised questions regarding the value and impact of the proposed amendments, the Commission staff requested, by letter dated August 25, 1976, the voluntary, one-time submission of the personnel monitoring data for 1975 by all NRC specific licensees. The letter also invited the licensees to provide an estimate of the cost of their effort (1) in man-hours, and (2) in total cost of preparing the report. The distributions of the 172 responses that estimated man-hours and of the 125 responses that estimated total cost indicated a median commitment of 2.75 minutes or $0.65 per monitored individual. The personnel monitoring and cost data have been published as NUREG-0419.

The Commission is convinced, based on 9 years of experience with reports filed by four categories of licensees pursuant to § 20.407 and based on the results of the one-time submission of data for 1975 by other categories of licensees, that it is necessary to the Commission's functions to receive the annual statistical summary reports. The data are essential to the evaluation of the risk of radiation exposure associated with activities conducted in licensed facilities. The data will permit evaluation of exposure trends. They also permit some assessment of the degree of radiation protection efficiency that is being maintained, one indicator of the effectiveness of the Commission's regulatory program. The Commission recognizes the diversity of programs conducted by licensees, but believes that there is sufficient basis for comparison of exposure experience among types of licensees and among licensees within each type. The NRC believes that licensees need to develop this information for their own evaluation and action in control and direction of their radiation safety programs. Consideration of the data led to the development of Regulatory Guides 8.8, "Information Relevant to Ensuring that Occupational Radiation Exposures at Nuclear Power Stations Will Be As Low As Is Reasonably Achievable," and 8.10, "Operation Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," and will assist in the identification of situations to be studied further in order that regulations and regulatory guides can be developed on action that should be taken in the design and operation of licensed facilities to assure that in-plant exposures are kept as low as is reasonably achievable. The data were used in the consideration of occupational exposure aspects of controlling radioactive effluent releases from nuclear powerplants in Appendix I, 10 CFR Part 50, and have been used to develop a variety of value/impact analyses. They may be used as one indicator in the assignment of priorities for inspection and enforcement actions. The data are being used to establish priorities with respect to the need for regulatory attention through consideration of the collective dose in addition to individual and average doses. In some cases, more regulatory attention may be required for licensees with larger collective doses than for licensees with larger individual doses.

It should be noted, however, that the personnel monitoring data do not permit evaluation of what occupational exposures are "as low as is reasonably achievable." Such evaluation requires study of the specific factors associated with a specific facility and activity.

The Commission has considered alternative methods of obtaining information on the number and exposure experience of individuals working in licensed facilities and found them to be unsatisfactory by reason of cost or data content. The burden on respondent licensees under the reporting requirement of § 20.407 will not be large and will, of course, be roughly proportional to the number of individuals monitored by a licensee. The Commission considers the burden well justified. However, the Commission has decided to impose the extended requirement only for a trial period of 2 years. That is, reports by all licensees are to be filled within the first quarter of calendar years 1979 and 1980, providing personnel monitoring data for the years 1978 and 1979, respectively. The Commission will evaluate the data for those 2 years, and the benefits derived therefrom and will consider whether or not to extend or otherwise modify the reporting requirement. A notice of proposed rulemaking will be published regarding any such extension or modification and opportunity for public comment will be provided. Note that the requirement for reporting by the four categories of licensees previously required to report, and now specified in § 20.408(a), as amended, will continue in any case.

The Commission does not consider it sufficient that licensees merely maintain exposures of individuals within the limits of 10 CFR Part 20, thus avoiding overexposures. Rather, § 20.1(c) states that licensees should make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as far below the limits specified in 10 CFR Part 20 as is reasonably achievable. There are, without doubt, many specific situations where occupational exposures are as low as reasonably achievable. However, because of the lack of data on exposures being experienced by a large fraction of licensees and the need to know the specific circumstances involved in order to determine when occupational exposures are as low as is reasonably achievable, the Commission believes that a categorical statement regarding any type of licensee or type of facility as achieving that goal would be premature and unfounded at this time.

The Commission recognizes the limitations of personnel monitoring devices and the possible differences between data obtained from routine monitoring programs and the actual doses received by individual workers. However, the Commission believes that current personnel monitoring measurements sufficiently character-

ize the radiation environment in which the individual works to provide an adequate basis for radiation protection evaluation purposes, and desires to be informed as to the estimated exposures actually being recorded.

The Commission also recognizes that statistical summary reports will not permit evaluation of the dose contribution from different types of activities within the licensee's program or identification of contributions to the total dose received during work with unlicensed sources of radiation. However, licensees are required (§ 20.1(b)) to control the possession and use of licensed material in such a manner that the total occupational dose received by individuals from both licensed and unlicensed sources in the licensee's possession does not exceed the standards in 10 CFR Part 20. Thus, licensees should monitor the individual's total occupational dose (§ 20.202), record the estimated dose in the individual's record (§ 20.401), and use the total dose estimate in preparing the annual statistical summary report required by § 20.407, as amended, and the termination report required by § 20.408, if applicable. Note that §§ 20.407 and 20.408 have been amended to change the recipient of the reports from the Director of Inspection and Enforcement to the Director of Management and Program Analysis, NRC.

The Commission has reminded each of the licensees who have been subject to the reporting requirement of the need to report each year, including a copy of the table of estimated whole body exposure ranges that may be used in filing the report. The Commission proposes to continue this practice. Licensees will be reminded that if personnel monitoring was not required to be provided to any individual (§ 20.202(a) or § 34.33(a)) during the calendar year, licensees are required to submit a simple statement to that effect, only. The Commission cannot determine from the issuance of a license whether personnel monitoring is or is not required, because radioactive material licensed for possession and use may not be procured, and licensed operations may be suspended such that monitoring is not required.

The simple negative report is included to reduce the number of cases in which followup action might be necessary in the absence of a report being filed by a licensee. The burden of a responding licensee in filing the negative report is very small. The data on personnel monitoring are summarized each year in a report to the Commission and are available to the public.

Discussions with several commercial dosimetry services indicate that there is very little need for more than 3 months in which to file the annual statistical summary report. It was indicated that sometimes delay may occur because of the late submission of dosimeters for processing, and that in some cases the exposure records are not summarized and the report prepared until after the first monitoring period in the new calendar year in an effort to include individuals whose dosimeters were not submitted on time for evaluation at the end of the year. Experience indicates that a very small number of "lost badges" and other causes of incomplete data will persist regardless of the date established for filing of the report. Further, it does not appear that the annual statistical summary report would be significantly improved by delaying the date for filing of the report. There should not be additional cost to licensees to process their data during the first calendar quarter of each year.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 553 of title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 20, are published as a document subject to codification.

1. Section 20.407 is revised to read as follows:

§ 20.407 Personnel monitoring reports.

Each person described in § 20.408 of this part shall, within the first quarter of each calendar year, submit to the Director of Management and Program Analysis, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the reports specified in paragraphs (a) and (b) of this section covering the preceding calendar year.[1] All other persons specifically licensed by the Commission shall, within the first quarter of calendar years 1979 and 1980, submit to the Director of Management and Program Analysis, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, the reports specified in paragraphs (a) and (b) of this section covering the preceding calendar years 1978 and 1979.[1, 2]

(a) A report of either (1) the total number of individuals for whom personnel monitoring was required under §§ 20.202(a) or 34.33(a) of this chapter during the calendar year; or (2) the total number of individuals for whom personnel monitoring was provided during the calendar year: *Provided, however,* That such total includes at least the number of individuals required to be reported under paragraph (a)(1) of this section. The report shall indicate whether it is submitted in accordance with paragraph (a)(1) or (a)(2) of this section. If personnel monitoring was not required to be provided to any individual by the licensee under §§ 20.202(a) or 34.33(a) of this chapter during the calendar year, the licensee shall submit a negative report indicating that such personnel monitoring was not required.

(b) A statistical summary report of the personnel monitoring information recorded by the licensee for individuals for whom personnel monitoring was either required or provided, as described in paragraph (a) of this section, indicating the number of individuals whose total whole body exposure recorded during the previous calendar year was in each of the following estimated exposure ranges:

Estimated whole body exposure range (rems)[3]	Number of individuals in each range
No measurable exposure	
Measurable exposure less than 0.1	
0.1 to 0.25	
0.25 to 0.5	
0.5 to 0.75	
0.75 to 1	
1 to 2	
2 to 3	
3 to 4	
4 to 5	
5 to 6	
6 to 7	
7 to 8	
8 to 9	
9 to 10	
10 to 11	
11 to 12	
12+	

[3] Individual values exactly equal to the values separating exposure ranges shall be reported in the higher range.

The low exposure range data are required in order to obtain better information about the exposures actually recorded. This section does not require improved measurements.

2. Section 20.408 is revised to read as follows:

§ 20.408 Reports of personnel monitoring on termination of employment or work.

(a) This section applies to each person licensed by the Commission to:

(1) Operate a nuclear reactor designed to produce electrical or heat energy pursuant to § 50.21(b) or § 50.22 of this chapter or a testing facility as defined in § 50.2(r) of this chapter;

(2) Possess or use byproduct material for purposes of radiography pursuant to Parts 30 and 34 of this chapter;

(3) Process or use at any one time, for purposes of fuel processing, fabrication, or reprocessing, special nuclear

[1] A licensee whose license expires or terminates prior to, or on the last day of the calendar year, shall submit reports at the expiration or termination of the license, covering that part of the year during which the license was in effect.

[2] The Commission will evaluate the data obtained for 1978 and 1979 pursuant to this paragraph, and the benefits derived therefrom and may take action, including publication of notice of proposed rulemaking, to extend or otherwise modify this reporting requirement.

material in a qantity exceeding 5,000 grams of contained uranium-235, uranium-233, or plutonium or any combination thereof pursuant to Part 70 of this chapter; or

(4) Possess or use at any one time, for processing or manufacturing for distribution pursuant to part 30, 32, or 33 of this chapter, byproduct material in quantities exceeding any one of the following quantities:

Radionuclide *	Quantity in curies
Cesium-137	1
Cobalt-60	1
Gold-198	100
Iodine-131	1
Iridium-192	10
Krypton-85	1,000
Prometium-147	10
Technetium-99m	1,000

*The Commission may require, as a license condition, or by rule, regulation or order pursuant to § 20.502, reports from licensees who are licensed to use radionuclides not on this list, in quantities sufficient to cause comparable radiation levels.

(b) When an individual terminates employment with a licensee describe in paragraph (a) of this section, or an individual assigned to work in such a licensee's facility but not employed by the licensee, completes the work assignment in the licensee's facility, the licensee shall furnish to the Director of Management and Program Analysis, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, a report of the individual's exposures to radiation and radioactive material, incurred during the period of employment or work assignment in the licensee's facility, containing information recorded by the licensee pursuant to §§ 20.401(a) and 20.108. Such report shall be furnished within 30 days after the exposure of the individual has been determined by the licensee or 90 days after the date of termination of employment or work assignment, whichever is earlier.

Effective date. These amendments become effective on December 13, 1978.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1242 (42 U.S.C. 5841).)

Dated at Washington, D.C. this 22nd day of September, 1978.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 78-27242 Filed 9-28-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 78N-0256]

MANDATORY UNIFORM EFFECTIVE DATE FOR FOOD LABELING REGULATIONS

Notice to Manufacturers, Packers, and Distributors

AGENCY: Food and Drug Administration.

ACTION: Rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing July 1, 1981, as its new mandatory uniform effective date for compliance with all final food labeling regulations that are published in the FEDERAL REGISTER after September 29, 1978. Because the current effective date is less than a year away, and because sufficient lead time is required for industry to make necessary labeling changes, the Commissioner is establishing July 1, 1981 as the new mandatory uniform effective date. All final food labeling regulations published in the FEDERAL REGISTER before September 29, 1978, which have July 1, 1979 as their effective date will continue to have a mandatory compliance date of July 1, 1979. Final regulations published in the FEDERAL REGISTER which had earlier effective dates (e.g., January 1, 1978) are already in effect and are not affected by this notice.

FOR FURTHER INFORMATION CONTACT:

Bob Lake, Bureau of Foods (HFF-302), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1254.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs periodically issues various regulations for packaged food. These regulations are designed to provide the consumer with information concerning the ingredients and nutritional qualities of the packaged food and to present the information in a uniform and understandable manner. Although some of these regulations permit labeling changes on a voluntary basis, others make labeling changes mandatory. In some cases, moreover, these regulations require extensive changes in current labeling. The economic impact on the food industry and ultimately on consumers, if these changes were required on a multiple piecemeal basis, might well be substantial over a period of time.

The Commissioner, therefore, believes that he should periodically establish a single mandatory effective date to be stated in all future regulations requiring changes in food labels unless special circumstances justify a different effective date. The single future date provides for an orderly and economical industry adjustment to new labeling requirements. A uniform effective date is also in the interest of consumers because the cost of multiple piecemeal label revisions that would otherwise be required would probably be passed on to consumers in the form of higher food prices.

The current uniform effective date for new final regulations affecting the labeling of food products is July 1, 1979. Foods initially introduced into interstate commerce on or after July 1, 1979 are required to comply with new food labeling regulations which have that date as their effective date. Because this current effective date is less than a year away, and because a sufficient lead time is required for industry to make necessary labeling changes, the Commissioner is establishing July 1, 1981 as the new mandatory uniform effective date for all final food labeling regulations published in the FEDERAL REGISTER after September 29, 1978. For those final food labeling regulations published before September 29, 1978, which have July 1, 1979 as their effective date, compliance is still required by July 1, 1979. Final regulations published in the FEDERAL REGISTER which had earlier effective dates (e.g., January 1, 1978) are already in effect and are not affected by this notice. For any food labeling for which special circumstances justify a different effective date, an appropriate effective date will be specified when the regulation is issued.

Dated: September 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27437 Filed 9-28-78; 8:45 am]

[4110-03]

SUBCHAPTER A—GENERAL

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Termination of Panel on Review of Hemorrhoidal Drugs

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: In accordance with the public advisory committee procedures, the Food and Drug Administration (FDA) announces the termination of the Panel on Review of Hemorrhoidal Drugs and amends the regulation listing the standing advisory committees. The Panel was terminated on August 21, 1978, because it has accomplished its intended purpose.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6057.

SUPPLEMENTARY INFORMATION: The Panel on Review of Hemorrhoidal Drugs reviewed and evaluated available data concerning the safety and effectiveness of nonprescription hemorrhoidal drug products. Its conclusions and recommendations will be published in a future issue of the FEDERAL REGISTER.

Accordingly, the Panel is no longer needed because the purpose for which it was created has been accomplished. On August 21, 1978, the Panel was abolished by the Secretary, Department of Health, Education, and Welfare, as the Commissioner of Food and Drugs requested.

Since this is a technical conforming amendment to part 14, the Commissioner of Food and Drugs finds that notice and procedures are unnecessary and that there is good cause for the rule to be effective immediately upon publication.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), part 14 (21 CFR part 14) is amended in § 14.100 List of Standing Advisory Committees, by deleting paragraph (c)(20)(i)(*h*) and marking it reserved.

Effective date. This amendment shall be effective September 29, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: September 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27102 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket No. 77C-0347]

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

PART 81—GENERAL SPECIFICATIONS AND GENERAL RESTRICTIONS FOR PROVISIONAL COLOR ADDITIVES FOR USE IN FOODS, DRUGS, AND COSMETICS

Bismuth Citrate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document "permanently" lists bismuth citrate as a color additive for use in cosmetics that color the hair on the scalp and exempts that color additive from certification. Combe, Inc., filed a petition for that use.

DATES: Effective October 31, 1978; objections by October 30, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5740.

SUPPLEMENTARY INFORMATION: A petition (CAP 4C0108) was filed by Combe, Inc., 1101 Westchester Avenue, White Plains, N.Y. 10604, for bismuth citrate. The petition proposed that the color additive regulations be revised in part 73 (21 CFR Part 73) to provide for the safe use of bismuth citrate as a color additive for use in cosmetic hair dyes. The notice of filing was published in the FEDERAL REGISTER of April 7, 1978 (43 FR 14737).

The Commissioner of Food and Drugs has evaluated the data in the petition and other relevant material and concludes that bismuth citrate is safe and suitable for use, under the conditions prescribed in this regulation, in cosmetic hair dyes and that certification is not necessary for the protection of the public health.

Bismuth citrate had been provisionally listed for use in cosmetics under § 81.1(g) (21 CFR 81.1(g)). The provisional listing was terminated in § 81.10(1) (21 CFR 81.10(1)) by a regulation published in the FEDERAL REGISTER of November 15, 1977 (42 FR 59064). Termination of listing resulted because of the failure of the petitioner to comply with the conditions attached to the postponement of the closing data in accordance with section 203(a)(2) of the transitional provisions of the color additive amendments of 1960 (title II, Pub. L. 86-618 (21 U.S.C. 376 note)). Recently, the petitioner submitted reports that satisfactorily established the safe use of bismuth citrate as a cosmetic hair dye ingredient. Therefore, with the permanent listing of bismuth citrate under § 73.2110 provided for by this amendment, the termination of provisional listing of bismuth citrate in § 81.10(1) will be deleted when this order becomes effective on October 31, 1978, unless this order is stayed by the timely filing of objections.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d))) and the transitional provisions of the color additive amendments of 1960 (title II, Pub. L. 86-618, sec 203, 74 Stat. 404-407 (21 U.S.C. 376 note)) and under authority delegated to the Commissioner (21 CFR 5.1), parts 73 and 81 are amended as follows:

1. Part 73 is amended in subpart C, by adding new § 73.2110 to read as follows.

§ 73.2110 Bismuth citrate.

(a) *Identity.* The color additive bismuth citrate is the synthetically prepared crystalline salt of bismuth and citric acid, consisting principally of $BiC_6H_5O_7$.

(b) *Specifications.* The color additive bismuth citrate shall conform to the following specifications and shall be free from impurities other than those named to the extent that those impurities may be avoided by good manufacturing practice:

Bismuth citrate, not less than 97 percent.
Mercury (as Hg), not more than 1 part per million.
Arsenic (as As), not more than 3 parts per million.
Lead (as Pb), not more than 20 parts per million.
Volatile matter, not more than 1 percent.

(c) *Uses and restrictions.* The color additive bismuth citrate may be safely used in cosmetics intended for coloring hair on the scalp, subject to the following restrictions:

(1) The amount of bismuth citrate in the cosmetic shall not be in excess of 0.5 percent (w/v).

(2) The cosmetic may not be used for coloring eyelashes, eyebrows, or hair on parts of the body other than the scalp.

(d) *Labeling.* (1) The label of the color additive bismuth citrate shall bear, in addition to any information required by law, labeling in accordance with the provisions of § 70.25 of this chapter.

(2) The label of a cosmetic containing the color additive bismuth citrate shall bear, in addition to other information required by law, the following statement, conspicuously displayed thereon:

Keep this product out of children's reach. Do not use on cut or abraded scalp. Do not use to color eyelashes, eyebrows, or hair on parts of the body other than the scalp. Wash hands thoroughly after each use.

(e) *Exemption from certification.* Certification of this color additive for the prescribed use is not necessary for the protection of the public health, and, therefore, batches thereof are exempt from certification requirements of section 706(c) of the act.

§ 81.10 [Amended]

2. In Part 81, § 81.10 Termination of provisional listing of color additives is amended by deleting paragraph (1) and marking it "reserved."

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 30, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the hearing clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective October 31, 1978, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Sec. 706 (b), (c), and (d), 74 Stat. 399-403 (21 U.S.C. 376 (b), (c), and (d)), and title II, Pub. L. 86-618, sec. 203, 74 Stat. 404-407 (21 U.S.C. 376 note).)

Dated: September 25, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27424 Filed 9-28-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77N-0118]

PART 131—MILK AND CREAM

Evaporated Milk, Sweetened Condensed Milk, Evaporated Skimmed Milk, and Sweetened Condensed Skimmed Milk; Standards of Identity; Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document confirms the effective date of the final regulation of May 19, 1978, that revised the standards of identity for sweetened condensed milk and evaporated milk and established standards of identity for sweetened condensed skimmed milk and evaporated skimmed milk based on consideration of the international standards developed by the Codex Alimentarius Commission for these foods.

DATES: Voluntary compliance may have begun July 18, 1978. Mandatory compliance for all products initially introduced into interstate commerce begins July 1, 1979.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs issued a final regulation in the FEDERAL REGISTER of May 19, 1978 (43 FR 21668) that amended the standards of identity for sweetened condensed milk and evaporated milk (21 CFR 131.120 and 131.130, respectively), and established standards of identity for sweetened condensed skimmed milk and evaporated skimmed milk (21 CFR 131.122 and 131.132, respectively). The standards were based on the recommended international standards for evaporated milk and evaporated skimmed milk (Codex Standard No. A-3 (1971)) and sweetened condensed milk and sweetened condensed skimmed milk (Codex Standard No. A-4 (1971)) which were submitted to the United States for consideration of acceptance by the Joint Food and Agriculture Organization/World Health Organization's Committee of Government Experts on the Code of Principles Concerning Milk and Milk Products, an auxiliary body of the Codex Alimentarius Commission. The new standards of identity for sweetened condensed skimmed milk and evaporated skimmed milk establish (1) requirements for mandatory ingredients, (2) provisions for optional ingredients such as stabilizers, emulsifiers, carriers for vitamins A and D, and characterizing flavoring ingredients, with or without coloring, and (3) requirements for label declaration of optional ingredients. The standards of identity for sweetened condensed milk and evaporated milk were amended to provide for the use of nutritive carbohydrate sweeteners in the optional characterizing flavoring ingredients. Further, for consistency with the international standards, the compositional requirements of these foods were amended to reduce the total solids requirement for evaporated milk from 25.5 percent to 25 percent by weight, and the milk fat requirement for sweetened condensed milk from 8.5 percent to 8 percent by weight.

No objections to the final regulation were received.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), notice is given that no objections were received. Compliance with the final regulation may have begun on July 18, 1978, and all products initially introduced into interstate commerce on or after July 1, 1979, shall fully comply.

Dated: September 22, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27422 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket No. 78P-0059]

PART 131—MILK AND CREAM

Repeal of Standard of Identity for Sour Half-and-Half Dressing

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document repeals the standard of identity for sour half-and-half dressing. The agency is taking this action because the name of the dressing could be misleading to consumers.

DATES: Effective November 28, 1978; objections by October 30, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Eugene T. McGarrahan, Bureau of Foods (HFF-415), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of March 17, 1978 (43 FR 11226), the Commissioner of Food and Drugs, on his own initiative, proposed to repeal the standard of identity for sour half-and-half dressing, § 131.189 (21 CFR 131.189). Although there were no objections to the standard for sour half-and-half dressing, the Commissioner proposed this action to be consistent with a separate action, published in the same issue of the FEDERAL REGISTER (43 FR 11150), that revoked the standard of identity for sour cream dressing. Because sour cream dressing could be fabricated from milk-derived ingredients rather than from "cream," the Commissioner concluded that use of the words "sour cream" in the name of a product that would not be required to contain sour cream (as defined in § 131.160 (21 CFR 131.160)) could be misleading to the consumer. Since sour half-and-half similarly is required to be made from "half-and-half similarly is required to be made from "half-and-half," which is defined in § 131.180 (21 CFR 131.180) as a food consisting of a mixture of milk and cream, the Commissioner also concluded that the use of the words "sour half-and-half" in the name of a product that could be fabricated from ingredients other than milk and cream could likewise be misleading to the consumer. He therefore proposed that the standard of identity for "sour half-and-half dressing" should be repealed. Interested persons were invited to submit comments on or before April 17, 1978. No comments have been received.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner (21 CFR 5.1), part 131 is amended by revoking § 131.189 sour half-and-half dressing.

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 30, 1978 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the hearing clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective November 28, 1978, except as to any provisions that may be stayed by the filing of proper objections. Notice of the filing of objections or lack thereof will be given by publication in the FEDERAL REGISTER.

(Secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)).)

Dated: September 25, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27423 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket Nos. 77F-0205; 75F-0082]

PART 177—INDIRECT FOOD ADDITIVES

Perfluorocarbon Resins

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The food additive regulations are amended to provide for both the use of lithium polysilicate and naphthalene sulfonic acid formaldehyde condensate, sodium salt as components of perfluorocarbon resin coatings intended for repeated use, and the use of ionizing radiation to produce a polytetrafluoroethylene resin lubricant powder. E.I. duPont de Nemours & Co. Inc., and ICI Americas Inc., filed petitions proposing such amendments. In addition, this final rule corrects an editorial error and clarifies the extraction requirements set forth in the regulation.

DATES: Effective date September 29, 1978; objections by October 30, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Notices published in the FEDERAL REGISTER of February 26, 1975 (40 FR 8242) and June 16, 1975 (40 FR 25502) announced that food additive petitions had been filed by E.I. duPont de Nemours & Co. Inc., Wilmington, Del. (FAP 4B2989) and ICI Americas Inc., Wilmington, Del. (FAP 3B2861) proposing that § 177.1550 (21 CFR 177.1550) be amended to provide for the safe use of lithium polysilicate as a component of perfluorocarbon resins (FAP 4B2989) and to exempt irradiated perfluorocarbon lubricant powders from the thermal instability index specification of § 177.1550(b)(1)(iii) (FAP 3B2861).

The notice announcing filing of the duPont petition was amended to propose the use of naphthalene sulfonic acid formaldehyde condensate, sodium salt as well as lithium polysilicate as components of perfluorocarbon resins. The amended notice appeared in the FEDERAL REGISTER of April 7, 1978 (43 FR 14738).

In the FEDERAL REGISTER of March 15, 1977 (42 FR 14302) the Food and

Drug Administration recodified and republished the food additive regulations, and transferred the subject regulation from § 121.2555 to its present designation under § 177.1550. However, the wording in paragraph (a)(2), which permits the use of substances "under applicable regulations in this part," was not appropriately revised, thus incorrectly indicating that only substances regulated in part 177 can be utilized in the production of perfluorocarbon resins. In the revision of § 177.1550 below, the Commissioner of Food and Drugs has corrected the wording (now paragraph (b)(3)) to indicate that materials listed in applicable regulations in parts 175 and 178 can also be used, subject to any limitations in those regulations.

Additionally, the Commissioner is modifying the extraction test procedures to prescribe more exactly the test conditions. There is no change in the extraction limitations.

Having evaluated data in the petitions and other relevant material, the Commissioner concludes that § 177.1550 should be amended as petitioned, except that the perfluorocarbon resin for producing irradiated lubricant powder is restricted to polytetrafluoroethylene because FAP 3B2861 deals only with that specific resin.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), part 177 is amended by revising § 177.1550 to read as follows:

§ 177.1550 Perfluorocarbon resins.

Perfluorocarbon resins identified in this section may be safely used as articles or components of articles intended to contact food, subject to the provisions of this section:

(a) *Identity.* For the purpose of this section perfluorocarbon resins are those produced by the homopolymerization and/or copolymerization of hexafluoropropylene and tetrafluoroethylene. The resins shall meet the specifications prescribed in paragraph (d) of this section.

(b) *Optional components.* The resins identified in paragraph (a) of this section as well as articles or coatings made from these resins may include the following optional components:

(1) Substances generally recognized as safe (GRAS) in food or food packaging subject to any limitations cited on their use.

(2) Substances used in accordance with a prior sanction or approval, subject to any limitations cited in the prior sanction or approval.

(3) Substances authorized under applicable regulations in this part and in parts 175 and 178 of this chapter and subject to any limitations prescribed therein.

(4) The following substances, subject to any limitations prescribed:

List of substances	*Limitations*
Lithium polysilicate containing not more than 20 weight pct silica, not more than 2.1 pct lithium oxide and having a maximum mole ratio of SiO_2/Li_2O of 8.5 to 1.	For use only as a component of repeated-use coatings not exceeding 1.2 mil in thickness where the coatings are thermally cured at minimum sintering temperatures of 700° F. Lithium extractives shall not exceed 0.1 mg per square inch of coating surface when tested in accordance with par. (e)(2) of this section.
Naphthalene sulfonic acid formaldehyde condensate, sodium salt.	For use only as a component of repeated-use coatings not exceeding 1.2 mil in thickness, and at a level not to exceed 0.4 weight pct of the coating.

(c) *Optional processing.* Poly- tetrafluoroethylene resins may be irradiated by either a cobalt-60 sealed source, at a maximum dose of gamma radiation not to exceed 7.5 megarads, or an electron beam at energy levels not to exceed 2.5 million electron volts with a maximum dosage of 7.5 megarads, to produce lubricant powders having a particle diameter of not more than 20 microns for use only as components of articles intended for repeated use in contact with food.

(d) *Specifications.* (1) *Infrared identification.* Perfluorocarbon resins can be identified by their characteristic infrared spectra.

(2) *Melt viscosity.* Perfluorocarbon resins have a melt viscosity of not less than 10^4 poises at 380° C as determined by American Society for Testing Materials Method D-1238-57T,[1] which is incorporated by reference. Melt viscosity of the copolymers shall not vary more than 50 percent within one-half hour at 380° C.

(3) *Thermal instability index.* The thermal instability index of the tetrafluoroethylene homopolymer shall not exceed 50 as determined by American Society for Testing Materials Method D-1457-56T,[1] which is incorporated by reference. The requirements of this paragraph do not apply to polytetrafluoroethylene resin lubricant powders described in paragraph (c) of this section.

(e) *Limitations.*[2] (1) Perfluorocarbon-molded articles having a surface area of 100 square inches or more and at least 50 mils thick shall be extracted at reflux temperatures for 2 hours separately with distilled water, 50 percent ethanol, *n*-heptane, and ethyl acetate.

(2) Perfluorocarbon coatings shall be applied to both sides of a 1.0-mil thick aluminum foil to a thickness of 1.0 mil after thermal curing at 750° F for 10 minutes. If a primer is used, the primer plus topcoat shall equal 1.0 mil after heat curing. Coating shall be extracted at reflux temperatures for 2 hours separately with distilled water, 8 percent ethanol, and *n*-heptane.

(3) The extracted surfaces shall meet the following extractability limits:

(i) Total extractives not to exceed 0.2 milligram per square inch.

(ii) Fluoride extractives calculated as fluorine not to exceed 0.03 milligram per square inch.

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 30, 1978, submit to the hearing clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective September 29, 1978.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)).)

Dated: September 25, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

NOTE.—Incorporation by reference was approved by the Director of the Office of the

[1] Copies are available from University Microfilms, Inc., 300 North Zeeb Rd., Ann Arbor, Mich. 48106.

[2] A more detailed procedure of extraction conditions is available from the Division of Food and Color Additives, HFF-330, Food and Drug Administration, 200 C Street SW., Washington, D.C. 20204.

Federal Register on August 3, 1978, and is on file in the Federal Register Library.

[FR Doc. 78-27426 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket No. 78N-0020]

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

Polyoxymethylene Homopolymer

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the food additive regulations to remove pH limitations and to increase the maximum temperature for use of polyoxymethylene homopolymer intended for food-contact use. E. I. Dupont de Nemours & Co. filed a petition for such use.

DATES: Effective September 29, 1978; objections by October 30, 1978.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

John J. McAuliffe, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C Street SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Notice was published in the FEDERAL REGISTER of February 28, 1978 (43 FR 8133) that a petition (FAP 7B3331) had been filed by E. I. Dupont de Nemours & Co., Wilmington, Del. 19898, proposing that § 177.2480 *Polyoxymethylene homopolymer* (21 CFR 177.2480) providing for food contact use of polyoxymethylene homopolymer be amended to remove any pH limitations for contact foods and to increase the maximum allowable use temperature from 160° F. to 250° F.

During evaluation of the petition, it was noted that the parenthetical reference to § 177.1500 in § 177.2480(b)(1)(ii) did not adequately identify the nylon 66/610/6 terpolymer. To correct this, the proportions of the nylon polymers making up the terpolymer are set out in § 177.2480(b)(1)(ii), and the parenthetical reference to § 177.1500 is deleted.

The Commissioner of Food and Drugs, having evaluated data in the petition and other relevant material, concludes that § 177.2480 should be amended as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner (21 CFR 5.1), part 177 is amended in § 177.2480 by revising paragraphs (b)(1)(ii) and (e)(2) to read as follows:

§ 177.2480 Polyoxymethylene homopolymer.

* * * * *

(b) * * *

(1) * * *

(ii) Nylon 66/610/6 terpolymer. Respective proportions of nylon polymers by weight are: 3/2/4.

* * * * *

(e) * * *

(2) Use temperature shall not exceed 250° F.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 30, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation shall become effective September 29, 1978.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)).)

Dated: September 22, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 78-27440 Filed 9-28-78; 8:45 am]

[4110-03]

SUBCHAPTER D—DRUGS FOR HUMAN USE

[Docket No. 78N-0250]

PART 436—TESTS AND METHODS OF ASSAY OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

PART 450—ANTITUMOR ANTIBIOTIC DRUGS

Doxorubicin Hydrochloride; High-Pressure Liquid Chromatographic Assay

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document revises the antibiotic drug regulations to provide for an improved method for determining the doxorubicin hydrochloride content of doxorubicin hydrochloride. The new method, high-pressure liquid chromatography, replaces the spectrophotometric assay method and the microbiological agar diffusion assay method for potency determination. The microbiological agar diffusion assay method will remain in the bulk drug monograph as a measure of microbiological activity. This regulation is intended to improve drug quality.

DATES: October 30, 1978; comments by October 30, 1978.

FOR FURTHER INFORMATION CONTACT:

Joan Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The Commissioner of Food and Drugs is revising the antibiotic drug regulations by replacing the current potency methods for doxorubicin hydrochloride with a high-pressure liquid chromatography assay. The Commissioner finds that the high-pressure liquid chromatography assay is more accurate and reliable than the microbiological agar diffusion assay and the spectrophotometric methods currently set forth in the regulations.

Since the drug is a microbiologically active product, the microbiological agar diffusion assay will remain as a measure of activity in the bulk drug monograph only.

The Commissioner advises that this revision does not affect the interim provisions published and made effective on August 26, 1977 (42 FR 43061) regarding the use of the LD_{50} toxicity test in the release of batches of doxor-

ubicin hydrochloride. Resolution of the problems associated with the LD_{50} test as discussed in that amendment is still pending.

Because this revision improves testing procedures, and the only two manufacturers affected have agreed to the change, the Commissioner finds for good cause that notice and public procedure are unnecessary and are not in the public interest. However, an opportunity is provided for submission of comments to determine whether the regulation should subsequently be modified or revoked. A copy of the agreement with the two manufacturers is on file with the Hearing Clerk (HFA-305), Food and Drug Administration, room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 5.1), parts 436 and 450 are amended as follows:

1. In part 436, new § 436.322 is added to read as follows:

§ 436.322 High-pressure liquid chromatographic assay for anthracycline antibiotics.

(a) *Equipment.* A suitable high-pressure liquid chromatograph, such as a Waters Associates Model 244 [1] or equivalent equipped with:

(1) A low dead volume cell 8 to 20 microliters;

(2) A light path length of 1 centimeter;

(3) A suitable ultraviolet detection system operating at a wavelength of 254 nanometers;

(4) A suitable recorder of at least 25.4 centimeter deflection;

(5) A suitable integrator;

(6) A 30-centimeter column having an inside diameter of 4.6 millimeters and packed with a suitable reverse phase packing such as: Waters Associates, Micro-Bondapak C18.[1]

(b) *Reagents.* (1) Solvent mixture: Water: acetonitrile (69:31).

(2) Mobile phase: Water: acetonitrile (69:31) adjusted to pH 2 with phosphoric acid. Filter the mobile phase through a suitable glass fiber filter or equivalent that is capable of removing particulate contamination to 1 micron in diameter. Degas the mobile phase just prior to its introduction into the chromatograph pumping system.

(3) Internal standard solution: Prepare a 2.0-milligram-per-milliliter solution of 2-naphthalenesulfonic acid in the solvent mixture.

(c) *Operating conditions.* Perform the assay at ambient temperature with a typical flow rate of 1.5 milliliters per minute. Use a detector sensitivity setting that gives a peak height for the reference standard that is at least 50 percent of scale. The minimum between peaks must be no more than 2 millimeters above the initial baseline.

(d) *Procedure.* Use the standard and sample solutions prepared as directed in the individual monographs for the drug being tested. Use the equipment, reagents, and operating conditions listed in paragraphs (a), (b), and (c) of this section. Inject 5 microliters of the standard solution into the chromatograph. Allow an elution time sufficient to obtain satisfactory separation of expected components (ordinarily this time is 20 minutes). After separation of the standard solution has been completed, inject 5 microliters of the sample solution into the chromatograph and repeat the procedure described for the standard solution. The elution order is: Void volume, internal standard, doxorubicin, dihydrodaunomycin, daunomycin, adriamycinone, dihydrodaunomycinone, bromodaunomycin, daunomycinone, and bisanhydrodaunomycinone.

(e) *Calculations.* Calculate the anthracycline content as directed in the individual monograph for the drug being tested.

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2. In part 450, § 450.24 is amended by revising paragraph (a)(1) (i) through (vi) and (3)(i); by redesignating paragraph (b)(1) (i) through (v) as (b)(2) (i) through (v) and revising redesignated paragraph (b)(2)(i); by adding a new (b)(1); by redesignating existing paragraph (b) (2), (3), and (4) as (b) (3), (4), and (5) and setting them forth below; by deleting paragraph (b)(6) and redesignating existing (b)(5) as (b)(6); and by revising (b)(7) to read as follows:

§ 450.24 Doxorubicin hydrochloride.

(a) * * *

(1) * * *

(i) Its doxorubicin hydrochloride content is not less than 900 micrograms and not more than 1,100 micrograms of doxorubicin hydrochloride per milligram on the anhydrous basis.

(ii) Its microbiological activity is not less than 900 micrograms and not more than 1,100 micrograms of doxorubicin hydrochloride per milligram on the anhydrous basis.

(iii) Its moisture content is not more than 4.0 percent

(iv) Its pH in an aqueous solution containing 5 milligrams per milliliter is not less than 3.8 and not more than 6.5.

(v) Its LD_{50}[2] in mice is not less than 8.0 and not more than 20.0 milligrams per kilogram.

(vi) It is crystalline.

* * * * *

(3) * * *

(i) Results of tests and assays on the batch for doxorubicin hydrochloride content, microbiological activity, moisture, pH, LD_{50}, crystallinity, and identity.

* * * * *

(b) * * *

(1) *Doxorubicin hydrochloride content (high-pressure liquid chromatography).* Proceed as directed in § 436.322 of this chapter, preparing the sample and standard solutions and calculating the doxorubicin hydrochloride content as follows:

(i) *Preparation of sample and standard solutions.* Accurately weigh approximately 25 milligrams of the sample and of the doxorubicin hydrochloride working standard and dissolve each in 25 milliliters of the internal standard solution prepared as directed in § 436.322(b)(3) of this chapter.

(ii) *Calculations.* Calculate the doxorubicin hydrochloride content as follows:

$$\text{Micrograms of doxorubicin hydrochloride per milligram} = \frac{\frac{R_u}{} \times \frac{W_s}{} \times \frac{P}{} \times 100}{\frac{R_s}{} \times \frac{W_u}{} \times (100-\frac{M}{})}$$

where:

R_u = Area of the doxorubicin hydrochloride sample peak/Area of the internal standard peak.

R_s = Area of the doxorubicin hydrochloride standard peak/Area of the internal standard peak.

W_s = Weight of the doxorubicin hydrochloride working standard in milligrams.

W_u = Weight of the sample in milligrams.

M = Moisture content of the sample in percent.

P = Potency of the doxorubicin hydrochloride working standard in micrograms per milligram.

(2) *Microbiological activity (microbiological agar diffusion assay)*—(i) *Preparation of inoculated plates.* To a sufficient amount of medium 5 (as described in § 436.102(b)(5) of this chapter), that has been melted and cooled to 48° C. to 50° C., add the amount of test organism H (prepared as described in § 436.103 of this chapter), that gives the clearest, sharpest zones of inhibition measuring not less than 12 millimeters in diameter when tested against a solution of doxorubicin working standard containing 10 micro-

[1] Available from Waters Associates, Inc., Maple St., Milford, Mass. 10757.

[2] The term "LD_{50}" refers to the dosage of the drug that should be expected to kill 50 percent of the animals that receive the drug.

grams of doxorubicin hydrochloride per milliliter.

* * * * *

(3) *Moisture.* Proceed as directed in § 436.201 of this chapter.

(4) *pH.* Proceed as directed in § 436.202 of this chapter, using an aqueous solution containing 5 milligrams per milliliter.

(5) LD_{50}—(i) *Sample solution.* Dissolve an accurately weighed portion of the sample with sufficent sterile distilled water to give a concentration of 2 milligrams of doxorubicin hydrochloride per milliliter (estimated).

(ii) *Procedure.* Select 50 male mice, weighing between 18 and 22 grams, of the Flanders Research Farms ICR/FRF-2 strain. Weigh them to the nearest 0.5 gram. Use mice at each of the following dose levels: 0.08, 0.10, 0.125, 0.16, and 0.20 milliliter of sample solution per 20 grams of body weight. Calculate the volume of solution to be given to each mouse and administer the appropriate volume intravenously at the rate of 0.5 milliliter per minute. Observe the mice daily for 14 days and record times of death. Estimate the LD_{50} and its 95 percent confidence limits by the method of Carrol S. Weil, published in Biometrics Vol. 8, No. 3, pages 249-263 (1952).[3]

(6) *Crystallinity.* Proceed as directed in § 436.203(a) of this chapter.

(7) *Identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section compares qualitatively to that of the doxorubicin hydrochloride working standard.

[3] Copies may be obtained from Managing Editor, "Biometrics," P.O. Box 5457, Raleigh, N.C. 27607.

3. In part 450, § 450.224 is amended by revising paragraphs (a)(3)(i)(*a*) and (b) (1) and (7) to read as follows:

§ 450.224 Doxorubicin hydrochloride for injection.

(a) * * *

(3) * * *

(i) * * *

(*a*) The doxorubicin hydrochloride used in making the batch for doxorubicin hydrochloride content, microbiological activity, moisture, pH, LD_{50},[2] crystallinity, and identity.

* * * * *

(b) * * *

(1) *Doxorubicin hydrochloride content (high-pressure liquid chromatography).* Proceed as directed in § 436.322 of this chapter, preparing the sample and standard solutions and calculating the doxorubicin hydrochloride content as follows:

(i) *Working standard solution.* Accurately weigh approximately 25 milligrams of the doxorubicin hydrochloride working standard and dissolve in 25 milliliters of the internal standard solution prepared as directed in § 436.322(b)(3) of this chapter.

(ii) *Sample solution.* Prepare the sample solution by rinsing the contents of the vial into an appropriate-sized volumetric flask with a sufficient amount of internal standard solution prepared as directed in § 436.322(b)(3) of this chapter, to obtain a concentration of 1.0 milligram of doxorubicin hydrochloride per milliliter.

(iii) *Calculations.* Calculate the doxorubicin hydrochloride content as follows:

$$\text{Doxorubicin hydrochloride content per vial in milligrams} = \frac{R_u \times W_s \times V \times P}{R_s \times 25 \times 1{,}000}$$

where:

R_u = area of the doxorubicin hydrochloride sample peak/area of the internal standard peak.

R_s = area of the doxorubicin hydrochloride standard peak/area of the internal standard peak.

W_s = weight of the doxorubicin hydrochloride working standard in milligrams.

V = volume in milliliters of the internal standard solution added to the vials.

P = potency of the doxorubicin hydrochloride working standard in micrograms per milligram.

* * * * *

(7) *Identity.* The high-pressure liquid chromatogram of the sample determined as directed in paragraph (b)(1) of this section, compares qualitatively to that of the doxorubicin hydrochloride working standard.

Effective date: This amendment shall become effective October 30, 1978; however, interested persons may, on or before October 30, 1978, file with the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments, in four copies and identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the office of the hearing clerk between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comments will be the subject of a further amendment.

(Sec. 507, 59 Stat. 463, as amended (21 U.S.C. 357).)

Dated: September 22, 1978.

MARY A. MCENIRY,
Assistant Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc. 78-27425 Filed 9-28-78; 8:45 am]

[6560-01]

SUBCHAPTER E—ANIMAL FEEDS, DRUGS, AND RELATED PRODUCTS

[FRL 977-7; FAP 8H5175/R40]

PART 561—TOLERANCES FOR PESTICIDES IN ANIMAL FEEDS ADMINISTERED BY THE ENVIRONMENTAL PROTECTION AGENCY

Bentazon

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule amends 21 CFR Part 561 by establishing a feed additive tolerance for residues of the herbicide bentazon in or on spent mint hay. The regulation was requested by the Interregional Research Project No. 4. This rule establishes a maximum permissible level for residues of bentazon in or on spent mint hay.

EFFECTIVE DATE: Effective on September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia Critchlow, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460, 202-755-2516.

SUPPLEMENTARY INFORMATION: On February 8, 1978, notice was given (43 FR 5425) that the Interregional Research Project No. 4 (IR-4), New Jersey State Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, N.J. 08903, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Idaho, Indiana, Montana, Oregon, Washington, and Wisconsin and the U.S. Department of Agriculture, had filed a petition (FAP 8H5175) with the EPA. This petition proposed that 21 CFR Part 561 be amended by establishing a regulation permitting combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3 - benzothiadiazin - 4(3*H*) - one - 2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on spent mint hay with a tolerance limitation of 4 parts per million (ppm) resulting from application of bentazon to growing mint. (A related document establishing a tolerance for residues of bentazon on mint hay appears elsewhere in today's FEDERAL REGISTER.) No comments were re-

ceived by the Agency in response to this notice of filing.

The data submitted in the petition and other relevant material have been evaluated, and it is concluded that the pesticide can be safely used in the prescribed manner when such use is in accordance with the label and labeling registered pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 7 U.S.C. 136 et seq.). The toxicological data considered in support of the proposed tolerance included a 2-year rat feeding study with a no-observable-effect level (NOEL) of 350 ppm, a three-generation rat reproduction study with an NOEL greater than 180 ppm, a rat teratogenicity study with an NOEL of 66.7 milligrams (mg)/kilogram (kg) of body weight (bw), a rat oral lethal dose (LD50) study, a 90-day feeding study with an NOEL of 300 ppm and a dominant lethal mutagenicity study in the mouse (negative at 195 mg/kg bw). No additional data is considered desirable to support the proposed tolerance, except extended mutagenicity tests. The acceptable daily intake (ADI) for bentazon is calculated based on the NOEL determined in the rat 2-year feeding study and employing a safety factor of 100; the ADI is 0.175 mg/kg bw/day. Since all previous tolerances for bentazon represent theoretically less than 1 percent of the ADI, and mint and mint oil are very minor components of the human diet, the proposed tolerance can be toxicologically supported.

Tolerances have previously been established for residues of bentazon on a variety of raw agricultural commodities at levels ranging from 3 ppm to 0.02 ppm. The metabolism of bentazon is adequately understood, and an adequate analytical method (gas chromatography with flame photometric detection) is available for enforcement purposes. No regulatory actions are currently pending against the continued registration of bentazon.

The pesticide is considered useful for the purpose for which a tolerance is being sought, and it is concluded that the tolerance of 4 ppm established by amending 21 CFR part 561 will protect the public health. Therefore, the regulation is being established as proposed.

Any person adversely affected by this regulation may, on or before October 30, 1978, file written objections with the Hearing Clerk, EPA, Room M-3708, 401 M Street SW., Washington, D.C. 20460. Such objections should be submitted and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective on September 29, 1978, 21 CFR part 561 is amended as set forth below.

(Sec. 409(c)(1), Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(c)(1)).)

Dated: September 22, 1978.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

Part 561, subpart A, is amended by adding the following new section:

§ 561.51 Bentazon; tolerances for residues.

A tolerance of 4 parts per million is established for combined residues of the herbicide bentazon (3 - isopropyl - 1*H* - 2, 1, 3 - benzothiadiazin - 4(3*H*) - one - 2, 2 - dioxide) and its 6- and 8-hydroxy metabolites in or on spent mint hay resulting from application of the herbicide to growing mint.

[FR Doc. 78-27413 Filed 9-28-78; 8:45 am]

[4110-03]

SUBCHAPTER F—BIOLOGICS

[Docket No. 78N-0151]

PART 601—LICENSING

Amendment of Comment Period

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends a section of the biologics regulations to extend the time within which interested persons may submit comments on biological products review panel reports. This change is being made to provide interested persons with more time to review and to comment on the voluminous data and proposals contained in the panel reports.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Al Rothschild, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: The biologics regulations, § 601.25(f)(4) (21 CFR 601.25(f)(4)), provide that any interested person may, within 60 days after publication of the proposed order in the FEDERAL REGISTER, file with the Hearing Clerk of the Food and Drug Administration written comments. The Commissioner is revising § 601.25(f)(4) to extend the comment period from 60 to 90 days to give interested persons more time to thoroughly review and comment on the proposed order as well as the panel report, which contains voluminous detailed data.

Therefore, under the Public Health Service Act (sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262)) and under authority delegated to the Commissioner (21 CFR 5.1), § 601.25 is amended by revising paragraph (f)(4) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * * *

(f) * * *

(4) The full report or reports of the panel to the Commissioner of Food and Drugs.

The summary minutes of the panel meeting or meetings shall be made available to interested persons upon request. Any interested person may within 90 days after publication of the proposed order in the FEDERAL REGISTER, file with the Hearing Clerk of the Food and Drug Administration written comments in quintuplicate. Comments may be accompanied by a memorandum or brief in support thereof. All comments may be reviewed at the office of the Hearing Clerk during regular working hours, Monday through Friday.

* * * * * *

Under the Administrative Procedure Act (5 U.S.C. 553(b) and (d)), the Commissioner concludes that notice, public procedure, and delayed effective date are unnecessary because the modification of § 601.25(f)(4) effected by this rule expands the opportunity for expression of public interest and thus creates no new restriction.

EFFECTIVE DATE: This regulation is effective September 29, 1978.

(Sec. 351, 58 Stat. 702, as amended (42 U.S.C. 262).)

Dated: September 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27238 Filed 9-28-78; 8:45 am]

[4410-09]

CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

Denial of Excepted Prescription Drug Status

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This is a final order issued by the Administrator of the Drug Enforcement Administration (DEA) to deny the application for an exception from certain provisions of the Controlled Substances Act applied for by Medics Pharmaceutical Corp. for the product, Medigesic Plus. The effect of the final order is to preserve the schedule III classification as applied to Medigesic Plus and other products of identical formulation.

EFFECTIVE DATE: Effective September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Howard McClain, Jr., Chief, Regulatory Control Division, Drug Enforcement Administration, telephone 202-633-1366.

SUPPLEMENTARY INFORMATION: A notice was published in the FEDERAL REGISTER on August 4, 1978 (43 FR 34503), proposing to deny the application for an exception from certain provisions of the Controlled Substances Act for the product, Medigesic Plus and other products of identical formulation and providing an opportunity to Medics Pharmaceutical Corp., or any other interested persons, to submit comments or objections in writing regarding this proposal on or before September 5, 1978. No comments were received in response to this proposal.

Therefore, under the authority vested in him by the Act and by regulations of the Department of Justice, the Administrator of the Drug Enforcement Administration hereby denies the application for exception applied for by Medics Pharmaceutical Corp. for Medigesic Plus and other products of identical formulations.

Dated: September 21, 1978.

PETER B. BENSINGER,
Administrator.

[FR Doc. 78-27510 Filed 9-28-78; 8:45 am]

[4510-27]

Title 29—Labor

SUBTITLE A—OFFICE OF THE SECRETARY OF LABOR

PART 40—FARM LABOR CONTRACTOR REGISTRATION

Issuance of Certificates of Registration with Housing Authorization

AGENCY: Department of Labor.

ACTION: Final rule.

SUMMARY: Regulations now require that a farm labor contractor who owns or controls housing used for migrant workers and who was not issued a certificate authorizing the housing of such workers shall apply for an amended certificate not more than 60 days nor less than 30 days before use of such housing. This may cause difficulties in housing U.S. workers and may result in under utilization of the domestic work force. This change eliminates the 30 to 60 day requirement for approval of housing, and should result in improved use of U.S. migrant labor.

DATES: As this amendment releases a restriction it shall be effective September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Solomon Sugarman, Chief, Branch of Farm Labor Law Enforcement, Division of Minimum Wage and Hour Standards, Wage and Hour Division, Room S-3504, New Department of Labor Building, 200 Constitution Avenue NW., Washington, D.C. 20210, telephone 202-523-7531.

SUPPLEMENTARY INFORMATION: Section 5 of the Farm Labor Contractor Registraiton Act, 7 U.S.C. 2044, provides safeguards for housing migrant workers by a farm labor contractor who owns or controls such housing. Certificates of registration issued to farm labor contractors may be with or without authorization to house migrant workers. Under § 40.20(b) permission to house migrant workers may be added to a certificate of registration which does not authorize such housing if an application is submitted not more than 60 days nor less than 30 days before use of such housing.

This provision in 29 CFR 40.20(b) should be, and is, changed because this subsection placed a requirement upon farm labor contractors which was burdensome and difficult to meet. This resulted in few farm labor contractors obtaining authorization to house workers. This appears to have caused difficulties in housing U.S. workers and may have resulted in under utilization of the domestic work force. It is important, and should be recognized, that with current levels of unemployment in the United States, jobs in farmwork should be first available to American citizens and barriers to their employment such as the 30-60 day requirement in 29 CFR 40.20(b) must be removed. By deleting the requirement that proof of housing safety and health be submitted between 30 and 60 days prior to actual use of the housing workers will not be adversely affected. Farm labor contractors must still adhere to the provisions of 29 CFR 40.51(e) which requires approval of such housing before its use. The Farm Labor Contractor Registration Act prohibits the use of aliens not lawfully admitted to the United States, and aliens who have not been authorized by the Attorney General to accept employment. It is contrary to the public interest that the Department maintain a rule which promotes the use of foreign nationals, when the statute was designed to alleviate employment problems encountered by American farmworkers. The rule change will allow a greater number of farm labor contractors to register housing, which will facilitate contractual agreements with users, resulting in an increase in employment opportunities for American workers.

This amendment deletes the proviso at the end of § 40.20(b) which reads:

> Provided, That such proof as prescribed herein will have been submitted not more than sixty (60) days or less than thirty (30) days before actual use or occupancy of the housing facilities to the regional office which had issued the initial certificate.

I find, on the basis of the above, that it is contrary to the public interest to publish this change as a proposal, with opportunity for comment, and accordingly the change is published as a final document.

This document was prepared under the direction and control of Herbert J. Cohen, Assistant Administrator, Office of Fair Labor Standards, Wage and Hour Division, Department of Labor.

Paragraph (b) of § 40.20 is amended, and paragraph (a) is included without amendment in order that paragraph (b) may be read in proper context as follows:

§ 40.20 Authorization to house migrant workers

(a) If an applicant for a certificate of registration is the owner of or will control facilities to be used for housing migrant workers during any period for which such a certificate is sought, said applicant shall submit—

(1) A statement identifying such facilities; and

(2) Written proof that the housing facilities comply with Federal Safety

and health standards as prescribed in either 20 CFR 620.4 or 29 CFR 1910.142 and applicable State standards of safety and health. Such written proof may be either a statement signed by the person to whom migrant workers are furnished by a farm labor contractor attesting that the housing facilites comply with Federal safety and health standards and also with applicable State safety and health standards, or a written statement containing an attestation with equal effect and signed by the applicant, or written statements issued by an authorized State and Federal Agency.

(b) should the required written proof be unavailable at the time of filing an application, the applicant must attest in writing that migrant workers in the applicant's crew will not be housed in any facilities under the ownership or control of the applicant that do not conform to all applicable Federal and State safety and health standards. In such event, if otherwise eligible, the applicant will be issued a certificate of registration without a housing authorization. This certificate may be amended to include an authorization to house migrant workers at such time as the required written proof is forthcoming.

Signed at Washington, D.C., on this 25th day of September 1978.

XAVIER M. VELA,
Administrator,
Wage and Hour Division.

[FR Doc. 78-27515 Filed 9-28-78; 8:45 am]

[3710-92]

Title 33—Navigation and Navigable Waters

CHAPTER II—CORPS OF ENGINEERS, DEPARTMENT OF THE ARMY

PART 207—NAVIGATION REGULATIONS

Cooper River and Tributaries, South Carolina, Restricted Areas

AGENCY: U.S. Army Corps of Engineers, DOD.

ACTION: Final rule.

SUMMARY: This document amends the regulations which establish restricted areas in the Cooper River and its tributaries, South Carolina. This amendment enlarges the restricted area in the vicinity of the Charleston Naval Shipyard to provide more effective security for that facility.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Ralph T. Eppard, 202-693-5070, or write Office of the Chief of Engineers, Forrestal Building, Attn: DAEN-CWO-N, Washington, D.C. 20314.

SUPPLEMENTARY INFORMATION: The proposed revision was published in the FEDERAL REGISTER on July 24, 1978 (43 FR 31955) with the comment period expiring on August 18, 1978. We received no comments and, accordingly, pursuant to the provisions of section 7 of the Rivers and Harbors Act approved August 8, 1917 (40 Stat. 266; 33 U.S.C. 1), the regulations in 33 CFR 207.164b are hereby amended as set forth below.

Dated: September 11, 1978.

MICHAEL BLUMENFELD,
Deputy Under Secretary of the Army.

§ 207.164b Cooper River and tributaries at Charleston, S.C.; restricted areas.

(a) The areas. (1) That portion of Cooper River beginning on the westerly shore at latitude 32°49'50", longitude 79°56'10"; thence to latitude 32°49'54", longitude 79°55'55"; thence to latitude 32°50'32", longitude 79°55'55"; thence to latitude 32°51'01", longitude 79°56'07"; thence to latitude 32°51'19", longitude 79°57'05"; thence to latitude 32°51'33", longitude 79°57'27"; thence to latitude 32°51'48.5", longitude 79°57'41.5"; thence to latitude 32°52'06", longitude 79°57'54"; thence to latitude 32°52'27", longitude 79°58'01"; thence to latitude 32°52'37", longitude 79°58'03"; and thence to the westerly shore at latitude 32°52'37", longitude 79°58'06".

(2) The reach of Shipyard Creek upstream from a line 300 feet from and parallel to the upstream limit of the improved Federal turning basin.

(3) That portion of the Cooper River beginning on the west channel edge at latitude 32°52'06", longitude 79°57'54"; thence to the easterly shore of the Cooper River at latitude 32°52'13", longitude 79°57'30"; thence proceeding along the easterly shore to latitude 32°51'37", longitude 79°56'38"; thence to latitude 32°51'19", longitude 79°57'05"; thence to latitude 32°51'33", longitude 79°57'27"; thence to latitude 32°51'48.5", longitude 79°57'41.5"; thence to latitude 32°52'06", longitude 79°57'54".

(4) That portion of Cooper River extending from the mouth of Goose Creek at Red Bank Landing, a distance of approximately 4.8 miles and the tributaries to Cooper River within the area enclosed by the following arcs and their intersections:

(i) Radius = 8255' center of radius latitude 32°55'45" N., longitude 79°45'23" W.

(ii) Radius = 3790' center of radius latitude 32°55'00" N., longitude 79°55'41" W.

(iii) Radius = 8255' center of radius latitude 32°55'41" N., longitude 79°56'15" W.

(iv) Radius = 8255' center of radius latitude 32°56'09" N., longitude 79°56'19" W.

(b) The regulations. (1) Unauthorized vessels and other watercraft shall not enter at any time the restricted areas described in paragraph (a) (1) and (2) of this section.

(2) Vessels and other watercraft entering the restricted area described in paragraph (a)(3) of this section shall proceed at normal speed and under no circumstances anchor, fish, loiter, or photograph until clear of the restricted area.

(3) Vessels and other watercraft other than those authorized by the Commanding Officer, Naval Ammunition Depot, entering the restricted area described in paragraph (a)(4) of this section shall proceed at normal speed and under no circumstances anchor, fish, or loiter in any way until clear of the restricted area. The area will be marked with suitable warning signs.

(4) The regulation in paragraphs (b) (1) and (2) of this section shall be enforced by the Commanding Officer, Southeastern Division, Naval Facilities Engineering Command, U.S. Naval Base, Charleston, S.C., and such agencies as he may designate.

(5) The regulation in paragraph (b)(3) of this section shall be enforced by the Commanding Officer, Naval Ammunition Depot, Charleston, S.C., and such agencies as he may designate.

AUTHORITY: 40 Stat. 266; 33 U.S.C. 1.

NOTE.—The Corps of Engineers has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107.

[FR Doc. 78-27444 Filed 9-28-78; 8:45 am]

[6560-01]

Title 40—Protection of Environment

[FRL 959-4]

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Connecticut Revision

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: EPA is approving a revision to the Connecticut State Implementation Plan (SIP) which updates chapter 8, Air Quality Surveillance, of the currently approved SIP to reflect the present configuration of the ambient monitoring network. This is an interim network to be in effect until such time as a modified SIP network may be required by revised EPA guidelines.

EFFECTIVE DATE: October 30, 1978.

FOR FURTHER INFORMATION CONTACT:

David Stonefield, Air Branch, EPA Region I, Room 2113, JFK Federal Building, Boston, Mass. 02203, 617-223-5609.

SUPPLEMENTARY INFORMATION: On June 30, 1977 the Governor of Connecticut submitted a revision to the SIP which updates chapter 8, Air Quality Surveillance, of the currently approved SIP to reflect the present configuration of the ambient monitoring network. However, since EPA's ambient monitoring guidelines are to be revised, this SIP revision is to be approved as an interim network; and any changes or relocations of monitoring instruments in the SIP network must be approved by EPA.

The revised ambient monitoring network was described in a notice of proposed rulemaking published in the FEDERAL REGISTER on April 8, 1978 (43 FR 16350) by the Regional Administrator which proposed approval of the revision. The network consists of 43 monitoring stations for total suspended particulates (TSP), 24 for sulfur dioxide (SO_2), 22 for nitrogen dioxide (NO_2), 12 for ozone (O_3), and 7 for carbon monoxide (CO).

Special features have been incorporated into the SIP network which provide for a telemetered air quality data system; "special purpose" monitoring sites for TSP; special study monitoring instruments for SO_2, CO, and O_3; continuous SO_2 sampling monitors operating year-round and SO_2 bubblers only during October through March; and collection of meteorological data.

Although there are fewer stations operating now than the number required in the original SIP, this is consistent with the draft policies established by EPA's standing air monitoring work group.

One letter of comment was received which expressed a need for expanded studies of photochemical and oxidant precursors. While this comment is beyond the scope of this revision, instruments for such special studies are available as noted in the special features of the revised network.

After evaluation of the State's submittal, the Administrator has determined that the Connecticut revision meets the requirements of the Clean Air Act and 40 CFR Part 51. Accordingly, this revision is approved as a revision to the Connecticut implementation plan.

Authority: Section 110(a) and 301 of the Clean Air Act, as amended (42 U.S.C. 7410 and 7601).

Dated: September 25, 1978.

DOUGLAS M. COSTLE,
Administrator.

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

Subpart H—Connecticut

1. A new subparagraph (8) is added in § 52.370(c) to read as follows:

§ 52.370 Identification of plan.

* * * * *

(c) The plan revisions listed below were submitted on the dates specified.

(8) Revision to chapter 8, Air Quality Surveillance, submitted on June 30, 1977 by the Governor.

[FR Doc. 78-27401 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 970-7]

PART 52—APPROVAL AND PROMULGATION OF STATE IMPLEMENTATION PLANS

Colorado Plan Revisions

AGENCY: U.S. Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: On May 5, 1977, the Governor of Colorado submitted to the Regional Administrator, Region VIII, of the Environmental Protection Agency (EPA), an addition to the Colorado State implementation plan (SIP) for the attainment and maintenance of national ambient air quality standards. Approval of the Colorado revision was proposed in the June 2, 1978, FEDERAL REGISTER (43 FR 24071). No comments on this proposal were received. The addition consists of a new Colorado Air Pollution Control Commission rule, "Procedural Rules for all Proceedings before the Air Pollution Control Commission and the Air Pollution Variance Board." The rule is a housekeeping measure for proceedings at the State level. The State submittal has been reviewed and found to be consistent with the substantive and procedural requirements of 40 CFR part 51, and the Clean Air Act. There is no impediment to approval of this revision as an addition to the Colorado SIP, and inclusion will assist the State in disseminating the rule to persons who will have interest in its requirements. Therefore, the Administrator approves the Colorado revision as set forth in this rulemaking, effective immediately upon promulgation.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Dale M. Wells, Technical Advisor, Planning and Operations Section, Air Programs Branch, U.S. Environmental Protection Agency, Region VIII, 1860 Lincoln Street, Denver, Colo. 80295, 303-837-3711.

AUTHORITY: Section 110 of the Clean Air Act, as amended (42 U.S.C. 7401, et seq.).

Dated: September 25, 1978.

DOUGLAS M. COSTLE,
Administrator.

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

Subpart G—Colorado

1. In § 52.320, paragraph (c)(10) is added as follows:

§ 52.320 Identification of plan.

* * * * *

(c) * * *

(10) Procedural rules for all proceedings before the Air Pollution Control Commission, submitted May 5, 1977, by the Governor.

[FR Doc. 78-27403 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 959-5]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

Massachusetts Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving revisions to regulations 7 and 9 of the Regulations for the Control of Air Pollution of the Massachusetts State implementation plan (SIP). Regulation 7, Open Burning, is revised to permit open burning of brush, cane, driftwood, and forest debris under certain conditions for 2 months of the year. Regulation 9, Dust and Odor, is revised by adding a requirement that mechanized street sweeping equipment must be equipped and operated with a suitable dust collection or

supression system. The revised regulations are applicable to all air pollution control districts in the State.

EFFECTIVE DATE: October 30, 1978.

FOR FURTHER INFORMATION CONTACT:

David Stonefield, Air Branch, EPA Region I, Room 2113, J. F. K. Federal Building, Boston, Mass. 02203, 617-223-5609.

SUPPLEMENTARY INFORMATION: On December 9, 1977, the Commissioner of the Massachusetts Department of Environmental Quality Engineering (the Massachusetts Department) submitted revisions to regulations 7 and 9 of the Regulations for the Control of Air Pollution of the State implementation plan (SIP). The revised regulations are applicable to all air pollution control districts (APCD's) in the State. The revisions to regulation 7 and regulation 9 were described in a notice of proposed rulemaking published in the FEDERAL REGISTER on June 8, 1978 (43 FR 24857) by the Regional Administrator, which proposed approval of the revision.

Regulation 7, Open Burning, of the presently approved SIP prohibits open burning of any combustible material except for certain purposes and under specifically stated conditions.

The revision adds as another permitted activity under this regulation, the open burning of brush, cane, driftwood, and forestry debris. Such burning is limited to the period from March 1 to May 1 of each year in the Berkshire APCD and from January 15 to March 15 of each year in the other APCD's. Open burning of grass, hay, leaves, and stumps, however, is specifically prohibited by this provision, and no open burning of brush, cane, driftwood, and forestry debris will be permitted in the cities and towns of Arlington, Belmont, Boston, Brookline, Cambridge, Chelsea, Chicopee, Everett, Fall River, Fitchburg, Holyoke, Lawrence, Lowell, Malden, Medford, New Bedford, Newton, Pittsfield, Somerville, Springfield, Waltham, Watertown, West Springfield, and Worcester. The conditions applicable to presently permitted open burning activities will also apply to the new activity. In addition, open burning of these materials must be conducted on land proximate to the place of generation, 75 feet from any dwelling, and between 10 a.m. and 4 p.m.

Finally, the revision adds a specific prohibition against conducting open burning at any refuse disposal facility. This provision is consistent with regulation 13 of the Regulations for the Disposal of Solid Waste by Sanitary Landfill, effective April 21, 1971, as well as with a proposed revision to the sanitary landfill regulations.

The conditions under which the revised open burning must be conducted were developed by the Massachusetts department as safeguards to minimize the impact of open burning on total suspended particulate (TSP) levels. Since open burning of these materials is prohibited in those areas with violations of the national ambient air quality standards (NAAQS) for TSP, the violations will not be exacerbated. The other conditions specified in the regulation are included to insure adequate dispersion of particulate emissions and to prevent fire hazards and nuisance conditions.

Regulation 9, Dust and Odor, of the presently approved SIP prohibits air pollution resulting from dust and odor generating operations and from handling, transportation, or storage of materials. Reasonable measures are required to prevent airborne particulate matter from construction, use, repair, or demolition of buildings, roads, driveways, or open areas.

The regulation is revised by adding a requirement that mechanized street sweeping equipment be equipped and operated with a suitable dust collection or suppression system. The revision specifies that the system be maintained in good operating condition.

Although street sweeping is considered a potential control measure for reducing high TSP levels resulting from reentrained road dust, it can in fact contribute to high TSP levels and cause local nuisance conditions when the dust control system with which virtually all of the mechanized street sweepers in the State are equipped, is not properly operated.

No letters of comment were received during the public comment period.

After evaluation of the State's submittal, the Administrator has determined that the Massachusetts revision meets the requirements of the Clean Air Act and 40 CFR, part 51. Accordingly, this revision is approved as a revision to the Massachusetts implementation plan.

AUTHORITY: Section 110(a) and 301 of the Clean Air Act, as amended (42 U.S.C. 7410 and 7601).

Dated: September 25, 1978.

DOUGLAS M. COSTLE,
Administrator.

Part 52 of Chapter I, Title 40, Code of Federal Regulations, is amended as follows:

Subpart W—Massachusetts

1. Section 52.1120(c) paragraph (16), is revised to read as follows:

§ 52.1120 Identification of plan.

* * * * *

(c) The plan revisions listed below were submitted on the dates specified.

(16) Revision to regulation 7 and regulation 9, submitted on December 9, 1977, by the Commissioner of the Massachusetts Department of Environmental Quality and Engineering.

[FR Doc. 78-27402 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 973-7]

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

North Carolina: Approval of Plan Revision

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The North Carolina implementation plan is revised by adding limits for emissions of sulfur dioxide (SO_2) and sulfuric acid (H_2SO_4) mist from the roasting of spodumene ore (a lithium-bearing mineral). Also, the description of the plan in the Code of Federal Regulations is being updated by adding an item previously omitted.

EFFECTIVE DATE: October 30, 1978.

ADDRESSES: Copies of the North Carolina implementation plan and the materials submitted by the State in connection with the present revision may be examined during normal business hours at the following locations:

Air Programs Branch, Environmental Protection Agency, Region IV, 345 Courtland Street NE., Atlanta, Ga. 30308.

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460.

Air Quality Section, Division of Environmental Management, North Carolina Department of Natural Resources and Community Development, 512 North Salisbury Street, P.O. Box 27687 Raleigh, N.C. 27611.

FOR FURTHER INFORMATION CONTACT:

Walter Bishop, Air Programs Branch, EPA Region IV, 345 Courtland Street NE., Atlanta, Ga. 30308, 404-881-3286 (FTS 257-3286).

SUPPLEMENTARY INFORMATION: On February 9, 1978, the North Carolina Environmental Management Commission, following notice and public hearing in conformity with 40 CFR 51.4, adopted regulations governing the roasting of spodumene ore. These were submitted to EPA's region IV office as a proposed implementation plan revision on February 14, 1978. In a notice of proposed rulemaking published in the FEDERAL REGISTER on May 5, 1978 (43 FR 19425), the Agency solicited public comment on the pro-

posed revision. No comments were received, however.

Two facilities in the State now process the lithium-bearing ore known as spodumene: Lithium Corp. of America in Bessemer City, and Foote Minerals in Shelby. On the basis of data supplied by these two sources, the North Carolina air quality agency performed diffusion modeling to estimate the ambient impact of their SO_2 and sulfuric acid mist emissions. The results were used to set the following emission limits for spodumene ore roasting: 9.7 pounds of SO_2 and 1.0 pound of H_2SO_4 mist per ton of ore roasted. These limits are contained in a new regulation, 15NCAC 2D .0527.

The State agency's modeling results indicate that implementation of these emission limits will not jeopardize the continued maintenance of the three national ambient air quality standards for sulfur dioxide, which are currently being met throughout the State.

The Administrator concurs, and the revision is hereby approved. This action is effective October 30, 1978.

At this time, the portion of 40 CFR Part 52 dealing with the North Carolina plan is also being updated to reflect the State's request for a delegation of authority to perform the technical and administrative portions of the PSD program.

This is not related to the revision being acted on today, but is being inserted to give a more accurate description of the North Carolina plan. It was inadvertently omitted at the time the delegation was announced (December 30, 1976, 41 FR 56805).

(Sec. 110(a) of the Clean Air Act (42 U.S.C. 7410(a)))

Dated: September 25, 1978.

DOUGLAS M. COSTLE,
Administrator.

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

Subpart II—North Carolina

Section 52.1770(c) is revised by renumbering subparagraph (17) as (18), by adding a new subparagraph (17), and by adding subparagraph (19) as follows:

§ 52.1770 Identification of plan.

* * * * *

(c) * * *

(17) Letter requesting delegation of Federal authority for the administrative and technical portions of the prevention of significant deterioration program, submitted on June 24, 1976, by the Secretary of the North Carolina Department of Natural and Economic Resources.

(18) Miscellaneous plan revisions, submitted on November 1, 1976, by the North Carolina Department of Natural and Economic Resources.

(19) Regulations governing emissions of sulfur dioxide and sulfuric acid mist from the roasting of spodumene ore, submitted on February 14, 1978, by the North Carolina Department of Natural Resources and Community Development.

[FR Doc. 78-27415 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 965-1]

PART 65—DELAYED COMPLIANCE ORDERS

Delayed Compliance Order for Citizens Gas & Coke Utility, Indianapolis, Indiana

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: By this rule, the Administrator of EPA approve a delayed compliance order to Citizens Gas & Coke Utility issued by the Indianapolis Air Pollution Control Board. The order requires the company to bring air emissions from its coke batteries at Indianapolis, Ind., into compliance with certain regulations contained in the federally approved Indiana State Implementation Plan (SIP). Citizens Gas & Coke Utility compliance with the order will preclude suits under the Federal enforcement and citizen suit provisions of the Clean Air Act for violations of the SIP regulations covered by this order.

DATES: This rule takes effect September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert B. Hurwitz, Attorney, U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Ill. 60604, telephone 312-353-2082.

SUPPLEMENTARY INFORMATION: On April 17, 1978, the Regional Administrator of EPA's Region V office published in the FEDERAL REGISTER (43 FR 16195) a notice setting out the provisions of a proposed State delayed compliance order for Citizens Gas & Coke Utility. The notice asked for public comments and offered the opportunity to request a public hearing on the proposed order. All public comments received supported issuance of the proposed order. No request for a public hearing was received in response to the proposed notice.

Therefore, a delayed compliance Order effective this date is approved by the Administrator of EPA pursuant to the authority of section 113(d)(2) of the Clean Air Act, 42 U.S.C. 7413(d)(2). The order places Citizens Gas & Coke Utility on a schedule to bring its coke batteries at Indianapolis, Ind., into compliance as expeditiously as practicable with regulations APC-3 and APC-5, parts of the federally approved Indiana State Implementation Plan. Citizens Gas & Coke Utility is unable to immediately comply with these regulations. The order also imposes interim requirements which meet sections 113(d)(1)(C) and 113(d)(7) of the Act, and emission monitoring and reporting requirements. If the conditions of the order are met, it will permit Citizens Gas & Coke Utility to delay compliance with the SIP regulations covered by the order until July 1, 1979.

Compliance with the order by Citizens Gas & Coke Utility will preclude Federal enforcement action under section 113 of the Act for violations of the SIP regulations covered by the order. Citizen suits under section 304 of the Act to enforce against the source are similarly precluded. Enforcement may be initiated, however, for violations of the terms of the order, and for violations of the regulations covered by the order which occurred before the order was approved by EPA or after the order is terminated. If the Administrator determines that Citizens Gas & Coke Utility is in violation of a requirement contained in the order, one or more of the actions required by section 113(d)(9) of the Act will be initiated. Publication of this notice of final rulemaking constitutes final Agency action for the purposes of judicial review under section 307(b) of the Act.

The provisions of the order will be summarized, as set forth below, in 40 CFR Part 65. The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedures for EPA's issuance, approval, and disapproval of an order under section 113(d) of the Act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 149876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

EPA has determined that the order shall be effective upon publication of this notice because of the need to immediately place Citizens Gas & Coke Utility on a schedule for compliance with the Indiana State implementation Plan.

(42 U.S.C. 7413(d), 7601.)

Dated: September 25, 1978.

DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, chapter I of title 40 of the Code of Federal Regulations is amended as follows:

PART 65—DELAYED COMPLIANCE ORDERS

1. By amending § 65.191 to read as follows:

§ 65.191 EPA Approval of State delayed compliance Orders issued to major stationary sources.

The State orders identified below have been approved by the Administrator in accordance with section 113(d)(2) of the Act and with this part. With regard to each Order, the Administrator has made all the determinations and findings which are necessary for approval of the order under section 113(d) of the Act.

Source	Location	Order No.	Date of FR proposal	SIP regulation involved	Final compliance date
Citizens Gas & Coke Utility	Indianapolis, Ind.	INDPLS APC-1.	Apr. 17, 1978.	Indiana APC-3, APC-5.	July 1, 1979

[FR Doc. 78-27404 Filed 9-28-78; 8:45 am]

[6560-01]

SUBCHAPTER E—PESTICIDE PROGRAMS

[FRL 977-8; PP 7E1976/R168]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Bentazon

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the herbicide bentazon on mint. The amendment to the regulations was requested by the interregional research project No. 4. This rule establishes a maximum permissible level for residues of bentazon on mint.

EFFECTIVE DATE: Effective on September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia Critchlow, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460 202-755-2516.

SUPPLEMENTARY INFORMATION: On July 14, 1978, the EPA published a notice of proposed rulemaking in the FEDERAL REGISTER (43 FR 30314) in response to a pesticide petition (PP 7E1976) submitted to the Agency by the interregional research project No. 4 (IR-4) New Jersey State Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, N.J. 08903, on behalf of the IR-4 technical committee and the Agricultural Experiment Stations of Idaho, Indiana, Montana, Oregon, Washington, and Wisconsin and the U.S. Department of Agriculture. This petition proposed that 40 CFR 180.355 be amended by the establishment of a tolerance for combined residues of the herbicide bentazon (3-isopropyl-1*H*-2,1,3-benzothiadiazin-4(3*H*)-one-2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the raw agricultural commodity mint at 1 part per million (ppm). (A related document establishing a feed additive regulation for residues of bentazon in or on spent mint hay appears elsewhere in today's FEDERAL REGISTER.) No comments or requests for referral to an advisory committee were received in response to this notice of proposed rulemaking.

It has been concluded, therefore, that the proposed amendment to 40 CFR 180.355 should be adopted without change, and it has been determined that this regulation will protect the public health.

Any person adversely affected by this regulation may, on or before October 30, 1978, file written objections with the Hearing Clerk, EPA, Room M-3708, 401 M Street SW., Washington D.C. 20460. Such objections should be submitted and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective on September 29, 1978, part 180, subpart C, § 180.355 is amended by adding a tolerance for residues of bentazon on mint at 1 ppm as set forth below.

(Sec. 408(e), Federal Food, Drug and Cosmetic Act (21 U.S.C. 346a(e)).)

Dated: September 22, 1978.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

Part 180, Subpart C, § 180.355 is amended in paragraph (a) by alphabetically inserting a tolerance of 1 ppm on mint in the table to read as follows:

§ 180.355 Bentazon; tolerances for residues.

(a) * * *

Commodity:	*Parts per million*
* * * * *	
Mint	1
* * * * *	

[FR Doc. 78-27412 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 977-3; PP 7E1999/R173]

PART 180—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

Methidathion

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes a tolerance for residues of the insecticide methidathion. The request was submitted by the Interregional Research Project No. 4. This regulation establishes a maximum permissible level for residues of methidathion on safflower seed.

EFFECTIVE DATE: Effective on September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia Critchlow, Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Washington, D.C. 20460, 202-755-2516.

SUPPLEMENTARY INFORMATION: On July 31, 1978, the EPA published a notice of proposed rulemaking in the FEDERAL REGISTER (43 FR 33263) in response to a pesticide petition (PP 7E1999) submitted to the Agency by the Interregional Research Project No. 4 (IR-4), P.O. Box 231, Rutgers University, New Brunswick, N.J. 08903, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of Arizona, California, and Texas. This petition proposed that 40 CFR 180.298 be amended by establishing a tolerance for residues of the insecticide methidathion (*O,O*-dimethyl phosphorodithioate *S*-ester with 4-(mercaptomethyl)-2-methoxy-Δ^2-1,3,4-thiadiazolin-5-one) in or on the raw agricultural commodity safflower seed at 0.5 part per million (ppm). No comments or requests for referral to an advisory committee were received in response to this notice of proposed rulemaking.

It has been concluded, therefore, that the proposed amendment to 40 CFR 180.298 should be adopted without change, and it has been determined that this regulation will protect the public health.

Any person adversely affected by this regulation may, on or before October 30, 1978, file written objections with the Hearing Clerk, EPA, Room M-3708, 401 M Street SW., Washington, D.C. 20460. Such objections should be submitted and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. A hearing will be granted if the objections are supported by the grounds legally sufficient to justify the relief sought.

Effective on September 29, 1978, part 180, subpart C, section 180.298 is amended by alphabetically inserting a tolerance for methidathion on safflower seed at 0.5 ppm.

(Sec. 408(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a(e)).)

Dated: September 22, 1978.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

Part 180, subpart c, § 180.298 is revised in its entirety by editorially revising the section into an alphabetized columnar listing and by alphabetically inserting the tolerance of 0.5 ppm on safflower seed, as follows:

§ 180.298 Methidathion; tolerances for residues.

Tolerances are established for residues of the insecticide methidathion (*O,O*-dimethyl phosphorodithioate, *S*-ester with 4-(mercaptomethyl)-2-methoxy-Δ^2-1,3,4-thiadiazolin-5-one) in or on the following raw agricultural commodities:

Commodity:	*Parts per million*
Alfalfa	6
Alfalfa, hay	6
Clover	6
Clover, hay	6
Cottonseed	0.2
Grapefruit	2
Grass	6
Grass, hay	6
Lemons	2
Oranges	2
Peaches	0.05
Pecans	0.05
Potatoes	0.2
Safflower seed	0.5
Sorghum, fodder	2
Sorghum, forage	2
Sorghum, grain	0.2
Sunflower seeds	0.5
Walnuts	0.05

[FR Doc. 78-27414 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 973-7]

PART 455—PESTICIDE CHEMICALS MANUFACTURING POINT SOURCE CATEGORY

AGENCY: Environmental Protection Agency.

ACTION: Amendments to final rule.

SUMMARY: On April 25, 1978, the Environmental Protection Agency promulgated effluent limitations guidelines for the pesticide chemicals manufacturing point source category (43 FR 17776). This amendment defines more clearly which pesticide active ingredients shall be considered in determining limitations for the organic pesticide chemicals parameter for subcategory 1 (40 CFR Part 455, Subpart A). In addition, this notice corrects an error in the appendix to the regulations regarding the number of facilities in subcategory 3 which were identified as achieving no discharge of process waste water.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

George M. Jett, Effluent Guidelines Division (WH-552), Office of Water and Hazardous Materials, Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-426-2497.

SUPPLEMENTARY INFORMATION: On April 25, 1978, EPA promulgated effluent limitations guidelines based on the application of the best practicable control technology currently available (BPT) for the pesticide chemicals manufacturing point source category (43 FR 17776; 40 CFR Part 455). Subpart A of the regulations (organic pesticide chemicals manufacturing subcategory) established limitations on the discharge of several pollutants, including pesticide chemicals. At that time, EPA believed that analytical methods were available which were capable of accurately measuring all pesticide active ingredients to levels below those in the final regulations. However, a reexamination of the record reveals that questions exist as to the reliability of some of these methods for measuring some of the chemicals. EPA is therefore amending these regulations to delete a number of active ingredients from coverage under the organic pesticide chemicals parameter. The amended regulation lists all active ingredients which shall be considered in calculating effluent limitations for organic pesticide chemicals. Calculation of effluent limitations for the remaining pollutant parameters is unaffected by this amendment, and will be based on production of all organic active ingredients not specifically excluded in 40 CFR § 455.20(a). The provisions of subparts B and C of these regulations are also unchanged.

An additional error exists in appendix B to the regulations (43 FR 17781). There, EPA stated that 44 randomly surveyed facilities in the pesticide chemicals formulating and packaging subcategory (40 CFR Part 455, Subpart C) were achieving no discharge of process waste waters. A review of the record indicates that actually 30 of these facilities are achieving no discharge. This discovery does not affect the conclusion that no discharge of process waste water represents BPT for this subcategory. All available information indicates that formulating and packaging facilities can achieve zero discharge regardless of type of process employed, geographical location, or age and size of plant. In addition to the above random survey, three independent sources of information support the conclusion that zero discharge is the predominant practice in the subcategory. Moreover, an industry survey of over 100 facilities found most achieving zero discharge.

Because these changes do not involve substantive or policy issues, but in fact refine the promulgated regulations, the Agency finds that notice and public comment are not required and that good cause has been shown for these changes to become effective upon promulgation.

Dated: September 21, 1978.

BARBARA BLUM,
Acting Administrator.

Subpart A, part 455 of chapter I, title 40, of the Code of Federal Regulations is amended to read as follows:

Subpart A—Organic Pesticide Chemicals Manufacturing Subcategory

§ 455.20 Applicability; description of the organic pesticide chemicals manufacturing subcategory.

(a) For the purpose of calculating effluent limitations for COD, BOD5, and TSS, the provisions of this subpart are applicable to discharges resulting from the manufacture of organic active ingredients, excluding the following: Allethrin, Benzyl Benzoate, Biphenyl, Bisethylxanthogen, Chlorophacinone, Coumafuryl, Dimethyl Phthalate, Diphacinone, Endothall Acid, EXD (Herbisan), Gibberellic Acid, Glyphosate, Methoprene, Naphthalene Acetic Acid, Phenylphenol, Piperonyl Butoxide, Propargite, 1,8 Naphthalic Anhydride, Quinomethionate, Resmethrin, Rotenone, Sulfoxide, Sodium Phenylphenate, Triazine compounds (both symmetrical and asymmetrical), and Warfarin and similar anticoagulants.

(b) For the purpose of calculating effluent limitations for organic pesticide chemicals, the provisions of this subpart are applicable to discharges resulting from the manufacture of the following organic active ingredients: Aldrin, BHC, Captan, Chlordane, DDD, DDE, DDT, Dichloran, Dieldrin, Endosulfan, Endrin, Heptachlor, Lindane, Methoxychlor, Mirex, PCNB, Toxaphene, Trifluralin, Azinphos Methyl, Demeton-O, Demeton-S, Diazinon, Disulfoton, Malathion, Parathion Methyl, Parathion Ethyl, Aminocarb, Carbaryl, Methiocarb, Mexacarbate, Propoxur, Barban, Chlorpropham, Diuron, Fenuron, Fenuron-TCA, Linuron, Monuron, Monuron-TCA, Neburon, Propham, Swep, 2,4-D, Dicamba, Silvex, 2,4,5-T, Siduron, Perthane, and Dicofol.

(c) The intermediates used to manufacture the active ingredients and active ingredients used solely in experimental pesticides are excluded from coverage in this subpart. Insecticidal pathogenic organisms such as Bacillus thuringiensis, insect growth hormones, plant extracts such as pyrethrins; sex attractants and botanicals such as Rotenone are also excluded from coverage in this subpart.

§ 455.21 Specialized definitions.

(a) "Organic active ingredients" means carbon-containing active ingredients used in pesticides, excluding metalloorganic active ingredients.

(b) "Total organic active ingredients" means the sum of all organic active ingredients covered by § 455.20(a) which are manufactured at a facility subject to this subpart.

(c) "Organic pesticide chemicals" means the sum of all organic active ingredients listed in § 455.20(b) which are manufactured at a facility subject to this subpart.

§ 455.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

In establishing the limitation set forth in this section, EPA took into account all information it was able to collect, develop, and solicit with respect to factors (such as age and size of plant, raw materials, manufacturing processes, products produced, treatment technology available, energy requirements, and costs) which can affect the industry subcategorization and effluent levels established. It is possible, however, that data which would affect these limitations have not been available and, as a result, these limitations should be adjusted for certain plants in this industry. An individual discharger or other interested person may submit evidence to the Regional Administrator (or to the State, if the State has the authority to issue NPDES permits) that factors relating to the equipment or facilities involved, the process applied, or other such factors related to such discharger are fundamentally different from the factors considered in the establishment of the guidelines. On the basis of such evidence or other available information, the Regional Administrator (or the State) will make a written finding that such factors are or are not fundamentally different for that facility compared to those specified in the Development Document. If such fundamentally different factors are found to exist, the Regional Administrator or the State shall establish for the discharger effluent limitations in the NPDES permit either more or less stringent than the limitations established herein, to the extent dictated by such fundamentally different factors. Such limitations must be approved by the Administrator of the Environmental Protection Agency. The Administrator may approve or disapprove such limitations, specify other limitations, or initiate proceedings to revise these regulations.

The following limitations establish the quantity or quality of pollutants or pollutant properties controlled by this paragraph which may be discharged from the manufacture of organic active ingredient by a point source subject to the provisions of this paragraph after application of the best practicable control technology currently available.

Effluent characteristics	Effluent limitations: Maximum for any 1 day	Effluent limitations: Average of daily values for 30 consecutive days shall not exceed—
COD	13.000	9.0000
BOD	7.400	1.6000
TSS	6.100	1.8000
Organic pesticide chemicals	.010	.0018
pH	(1)	(1)

(1) Within the range of 6.0 to 9.0.

NOTE.—For COD, BOD5, and TSS, metric units: Kilogram/1,000 kg of total organic active ingredients. English units: Pound/1,000 lb of total organic active ingredients. For organic pesticide chemicals—metric units: Kilogram/1,000 kg of organic pesticide chemicals. English units: Pound/1,000 lb of organic pesticide chemicals.

[FR Doc. 78-27409 Filed 9-28-78; 8:45 am]

[1505-01]

[FRL 955-8]

PART 423—STEAM ELECTRIC POWER GENERATING POINT SOURCE CATEGORY

Amendment to BPT Variance Clause

NOTE.—This document originally appeared at 43 FR 43023, September 22, 1978, and is being republished today to correct several typographical errors.

AGENCY: Environmental Protection Agency.

ACTION: Final amendments to rules.

SUMMARY: EPA is issuing amended regulations under the Clean Water Act which apply to the steam electric power industry. The amendments provide, contrary to EPA's original position, that economic factors are legally relevant when considering a powerplant's request for a variance from national effluent limitations guidelines. EPA has changed its original position in order to comply with a judicial decision.

DATE: The amendments are effective on September 21, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward A. Kramer (EN-336), Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460, 202-755-0750.

SUPPLEMENTARY INFORMATION:

I. Background

A. EPA's original variance clause

On October 8, 1974, EPA published regulations under the Clean Water Act setting forth best practicable control technology (BPT) effluent limitations guidelines for the steam electric power industry. 40 CFR Part 423, 39 FR 3686 et seq.

For each subcategory in the power industry category, there was a "variance clause." 40 CFR 423.12(a), 423.22(a), 423.32(a) and 423.42 (introductory paragraph). This clause allowed case-by-case variances from national guidelines where one could show that certain plant-specific factors—such as age or size of the plant—were "fundamentally different" from the factors EPA considered in setting the national guidelines. The variance clause did not specify whether plant-specific economic factors could be considered.

Essentially the same variance clause was included in the BPT effluent limitations guidelines for almost all industries. On August 20, 1974, EPA published a legal interpretation which ruled that economic factors could not be considered in applying this standard variance clause. 39 FR 30073.

B. The fourth circuit's appalachian order

On July 16, 1976, the U.S. Court of Appeals for the Fourth Circuit issued an opinion in response to various legal challenges to EPA's BPT (and other) regulations for the steam electric power industry. *Appalachian Power Co.* v. *Train*, 545 F.2d 1351. The court rejected EPA's exclusion of economic factors from the steam electric BPT variance clause. A request by EPA for recall of mandate as to this portion of the Court's opinion was denied (one judge dissenting) on September 26, 1977.

C. EPA's response to the fourth circuit's order

After the court's opinion was issued, EPA changed its position with regard to the steam electric power industry. On March 3, 1978 (43 FR 8812), EPA proposed clarifications to the steam electric variance clause to formalize its changed position.

As proposed, the variance clause allowed the permit issuer to consider "significant cost differentials" and other economic factors applicable to the particular source involved. The clause also specified that the August 20, 1974 legal interpretation would not be applicable to steam electric powerplants.

EPA requested that written public comments be submitted by April 3, 1978. The following parties submitted comments:

1. Consumers Power Co.
2. Richard J. Criqui, Jr.
3. Duke Power Co.
4. Natural Resources Defense Council (NRDC).
5. Synthetic Organic Chemical Manufacturers Association (SOCMA).
6. Union Carbide.
7. Utility Water Act Group (UWAG).

After considering all comments carefully, EPA has decided to issue the final variance clause amendments in the same form as they were proposed.

II. Response to Public Comments

A. Consideration of effluent reduction benefits

The proposed variance clause allowed case-by-case consideration of "significant cost differentials." Several commenters criticized EPA for failing to specify that "effluent reduction benefits" were to be weighed against costs in each case.

Upon examination, these criticisms are apparently derived from the commenters' desire for variances based upon receiving water quality. Such types of variances, however, are plainly not authorized by the Act. As explained in detail in the Administrator's decision *In the Matter of Louisiana—Pacific Corp.* and *Crown Simpson Pulp Co.*, 10 ERC 1841 (September 15, 1977), the Act does not allow relaxations of BPT limitations based upon case-by-case variations in water quality impact.

EPA believes that the wording of the proposed regulation is fully consistent with the *Appalachian* decision. In fact, EPA's wording was taken *verbatim* from the court's opinion:

> In requiring that EPA give weight to the relevant statutory factors in developing a subsequent variance provision, we in no way intend to imply that EPA's regulations must provide for a detailed cost-benefit analysis at the permit granting stage. As we indicated in *duPont*, * * * an overall cost-benefit analysis for each category or subcategory satisfies the mandate of § 304 in this regard. *The variance provision should, however, allow the permit issuer to consider significant cost differentials of the particular point source involved.* 545 F.2d at 1360, n. 23 [emphasis added].

B. Limitation to "fundamentally different factors"

UWAG argues that the proposed variance clause improperly fails to distinguish between "facts" and "factors." UWAG states in concluding its argument that "the variance clause must turn on consideration of plant-specific variables, on *facts* which are fundamentally different from those used in establishing the limitations." [UWAG's emphasis.]

It is not clear to EPA what difference of opinion exists between EPA and UWAG. If UWAG fears that plant-specific variables may not be considered, then it has misinterpreted the clause. As EPA stated in proposing the amendment:

> This clause allows case-by-case variances from national guidelines where one can show that certain *plant-specific* factors—such as age or size of the plant—are "fundamentally different" from the factors considered in setting the national guidelines. 43 FR at 8812.

Alternatively, if UWAG fears that by the use of the word "factors," EPA intended to foreclose consideration of plant-specific "facts," UWAG is mistaken. Site-specific *facts* which are fundamentally different from the facts considered by EPA in applying the relevant statutory factors (i.e., raw materials, energy requirements, size of plant), may qualify a facility for a variance. In this sense, "facts" and "factors" mean the same thing.

If, however, UWAG is arguing that any plant-specific fact—even one which does not relate to the statutory factors EPA considered in formulating the regulations—should qualify a facility for a variance, then EPA disagrees with UWAG. Such an interpretation would be incompatible with the "goal of uniformity" in industrywide BPT limitations, *duPont* v. *Train*, 97 S.Ct. 965, 975 (1977), for there are unique site-specific facts at every steam electric plant in the United States.

The *Appalachian* opinion, in fact, directs that EPA's new variance clause take into consideration the "statutory *factors*" in sections 301(c) and 304. 545 F.2d at 1360 [emphasis added]. And in another case discussing national BPT limitations, the Fourth Circuit said that "the specified *factors* [in section 304] shall be applied by the permit issuer in determining whether the presumptively valid effluent limitations should apply to a particular source of discharge." *DuPont* v. *Train*, 541 F.2d 1018, 1030 [4th Cir. 1976, emphasis added].

C. Illegality of proposal

NRDC argued that the proposed variance clause is illegal because section 301(c), which provides the exclusive means for case-by-case economic hardship modifications, is limited by its terms to 1983-84 "best available technology" (BAT) limitations as distinguished from BPT. EPA cannot dispute this argument. As stated in the March 3 proposal at 43 FR 8813:

> EPA continues to believe that with respect to variances from national effluent limitations guidelines, economic factors may be considered only in § 301(c) proceedings to modify [BAT] requirements.

Nevertheless, EPA is compelled by the court's order in *Appalachian* to include section 301(c) factors into the BPT variance clause for steam electric powerplants. The court's order relates only to the power industry, however, so EPA has rejected the arguments of SOCMA and Union Carbide that this revision be made applicable to all industries.

D. APPLICATION TO BEST AVAILABLE TECHNOLOGY ("BAT") AND NEW SOURCE PERFORMANCE STANDARDS ("NSPS")

Consumers Power Co. stated that the proposal was "deficient" because it did not apply to BAT or NSPS. (BAT and NSPS limitations are generally more stringent than BPT limitations.) The *Appalachian* Court, however, specifically rejected such an argument as to BAT. 545 F2d. at 1380. As to NSPS, the Supreme Court ruled in *duPont* v. *Train*, 97 S.Ct. 965 (1977) that variances were improper. 97 S.Ct. at 980. On September 26, 1977, the *Appalachian* Court recalled its mandate as to NSPS variances in response to the Supreme Court's decision.

E. STATES' RIGHTS

Duke Power Co. argued that EPA should require States which have a permit-issuing authority to consider economic factors when evaluating variance requests. Such a requirement would in EPA's view be inconsistent with the Act.

As noted in the March 3 proposal at 43 FR 8813, section 510 of the Act preserves the States' rights to impose more stringent limitations than required by Federal law. While one State may in its discretion refuse to relax nationally-applicable BPT regulations on the basis of site-specific economic factors, another State may allow relaxations to the fullest extent permissible under the Act. Section 510 insures that States have this freedom of choice.

Because States are free to ignore site-specific economic factors if they choose, it would be meaningless for EPA to require States to consider such factors.

III. EFFECTIVENESS

A. TRANSITIONAL PROVISIONS

Because there has been some confusion with respect to BPT variances for steam electric plants since the *Appalachian* remand, EPA agrees with UWAG that a new 60-day application period should be provided. Until November 21, 1978, any steam electric plant may apply to the appropriate permitting authority for a variance under today's amended clause. (As provided in 40 CFR 423.12(a), 423.22(a), 423.32(a), and 423.42, variances recommended by States must be approved by EPA before they become effective.)

Such an application will not automatically stay any enforcement proceeding which EPA has initiated or may initiate against the applicant. EPA will consider in each case whether a variance request is merely a procedural after-thought designed for delay. In this regard, EPA will consider whether a variance request is likely to succeed on the merits, whether the applicant was aware that EPA has been processing steam electric BPT variance requests for some time, and whether the applicant has made any effort to work out its problems with the appropriate enforcement authorities. It should be noted that any facility which is now in compliance with a BPT limitation may not rely upon a variance application as an excuse for falling out of compliance.

B. IMMEDIATE EFFECTIVENESS

In order to provide an immediate opportunity for applications under the amended regulations and to expedite final resolution of such applications, I hereby find good cause to make these amendments effective immediately.

(Sec. 501(a), Clean Water Act, 33 U.S.C. 1361(a).)

Dated: September 15, 1978.

DOUGLAS M. COSTLE,
Administrator.

§§ 423.12, 423.22, 423.32, and 423.42 [Amended]

40 CFR Part 423 is amended by adding the following two sentences to the end of §§ 423.12(a), 423.22(a), 423.32(a), and 423.42 (introductory paragraph):

* * * * *

* * * In accordance with the decision in *Appalachian Power Co.* v. *Train*, 545 F.2d 1351, 1358–60 (4th Cir. 1976), EPA's legal interpretation appearing at 39 FR 30073 (1974) shall not apply to this paragraph. The phrase "other such factors" appearing above may include significant cost differentials and the factors listed in section 301(c) of the Act.

[FR Doc. 78-26582 Filed 9-21-78; 8:45 am]

[4110-35]

Title 42—Public Health

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 462—GRANTS TO PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Designation of Alternate PSRO's

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

ACTION: Final rule.

SUMMARY: This rule sets forth selection criteria and other conditions for the designation of alternate professional standards review organizations (PSRO's) where physician groups that qualify for designation as priority PSRO's are not available in a PSRO area. It implements section 1152(b)(1)(B) of the Social Security Act. The purpose of the criteria is to assure that the designated organization will be professionally competent to carry out PSRO responsibilities and to facilitate designation of PSRO's in every PSRO area.

DATES: Effective on September 29, 1978.

FOR FURTHER INFORMATION, CONTACT:

Beth Giebelhaus, 202-245-2196.

SUPPLEMENTARY INFORMATION:

BACKGROUND

Section 1152 of the Social Security Act requires the Secretary to designate qualified organizations as PSRO's. The Act specified two categories of qualified organizations. These two categories are referred to in these regulations as: (1) Priority organizations; and (2) alternate organizations.

Priority organizations are groups that are composed exclusively of physicians ("physician groups") and that meet the requirements of section 1152(b)(1)(A). Alternate organizations are public, nonprofit private, or other agencies or organizations that are not necessarily composed of physicians and that meet the less stringent organizational requirements of these regulations. Priority organizations are preferred for designation as PSRO's. Prior to January 1, 1978, the law authorized us to designate only priority organizations, except in a few PSRO areas as provided by section 108 of Pub. L. 94-182. Even now, we may not renew a grant to an alternate PSRO if a qualified priority organization (that has not been previously designated) applies and we determine that designating the priority organization will

result in a substantial improvement in the performance of PSRO duties and functions in the area.

DESIGNATION OF ALTERNATE PSRO'S

There are two situations that justify the designation of an alternate PSRO. The first is a PSRO area where no priority organization has applied and been found qualified. The second is the need to replace a poorly performing priority organization, where no other priority organization applies and is qualified.

The criteria established by these regulations focus on the ability of an organization to act as a PSRO rather than on the nature of the organization itself. We want as many types of organizations as is consistent with congressional intent to be able to qualify for designation as alternate PSRO's. Applicants for designation as alternate PSRO's may be medical organizations (including, under certain circumstances, physician groups), State or local health departments, other State agencies, or medical schools. When none of these apply, carriers, intermediaries, and other health insurers will be considered.

DISCUSSION OF PUBLIC COMMENTS

On January 27, 1978, a notice of proposed rulemaking was published in the FEDERAL REGISTER (43 FR 3796). We received comments from 15 organizations and individuals. All comments were considered in preparing the final rule. These comments, our responses to them, and the changes from the proposed rule, are discussed below. Some of the changes were the result of comments. Others were needed to eliminate ambiguity in some provisions.

1. ROLE OF MEDICAL SOCIETIES

Two commenters suggested that medical societies be eligible for designation as alternate PSRO's, which would have been prohibited by the NPRM.

We have clarified the regulation on this point. As revised, a medical society that represents the largest number of physicians in the PSRO area cannot, under any circumstances, be designated as an alternate PSRO. However, another group of physicians in the PSRO area, which might be considered to be a medical society, can be designated as an alternate PSRO under the circumstances discussed below in comment number 3. If a group of physicians is designated as the alternate PSRO, it is expected that they will work towards meeting the requirements as a priority PSRO.

Our reasons for excluding the major medical society from being an alternate PSRO are as follows:

Medical societies were clearly the organizations expected by Congress to sponsor physician groups that would qualify under section 1152(b)(1)(A). The Senate Finance Committee stated: "Physician organizations or groupings would be completely free to undertake or decline assumption of the responsibilities of organizing a PSRO. If they decline, the Secretary would be empowered to seek *alternate applicants* from among *other* medical organizations * * *" (Emphasis added. S. Rept. 92-1230, p. 259.)

We have formally requested State and local medical societies to sponsor PSRO's in their respective designated areas. We view their failure to do so as an indication of lack of interest in, or opposition to, the PSRO program. If these medical societies were permitted to apply for designation as alternate PSRO's, it might discourage them from sponsoring priority organizations. This would be contrary to the intent of the Congress to limit the role of such organizations in the PSRO program to that of sponsoring and supporting priority organizations.

2. PRIORITY OF CARRIERS, INTERMEDIARIES AND OTHER HEALTH INSURERS

The proposed rule would have given health insurers priority over other qualified organizations located outside the State in which the PSRO area is located. While one commenter suggested that health insurers be given a higher priority, several others recommended that they be designated only as a last resort.

We have reconsidered our position in the light of expressed legislative intent. The Senate Finance Committee, after listing several potential candidates for designation as alternate PSRO's, stated that "failing all else, carriers and intermediaries or other health insurers" could be sought. (S. Rept. No. 92-1230, p. 260.) Section 462.5(d) of the final rule carries out that intent by assigning the lowest priority to all health insurers.

3. DESIGNATION OF PHYSICIAN GROUPS AS ALTERNATE PSRO'S

The proposed rule would have limited designation of physician groups as alternate PSRO's to existing PSRO's and to organizations in areas where the organizations representing the largest number of doctors of medicine or osteopathy in the area had taken a formal position of opposition to, or noncooperation with, the PSRO program. Two commenters recommended that all physician composed organizations be eligible to become alternate PSRO's, regardless of whether the medical society had clearly opposed the program. This recommendation was not accepted for the following reasons. The preference for priority PSRO's established by Congress would lose its meaning if a physician group could ignore the statutory requirements for a priority PSRO and still be designated as an alternate PSRO. This can be justified only if the group's failure to satisfy the requirements for priority organizations can reasonably be attributed to the opposition of organized medicine to the PSRO program. For example, there are several physician groups that have been trying, for up to 4 years, to qualify as priority organizations, but have failed to meet the requirement that their membership include 25 percent of the physicians in their areas. It is likely that the inability to achieve the required membership is due to the active opposition of the State and local medical societies. We believe this opposition to be the major obstacle that Congress wished to overcome by requiring designation of alternate PSRO's after a period of time during which only physician groups could be designated. This congressional intent was reiterated in the 1975 amendment (sec. 108(b) of Pub. L. 94-182), which permits us to forego notification and polling of physicians before designating PSRO's in any area where the medical society has taken a formal position of opposition to the PSRO program.

4. EFFECTIVE DATE OF OPPOSITION BY MEDICAL SOCIETIES

The proposed rule did not indicate when opposition must have occurred. The final regulation makes it clear that if at *any time* the organization representing the largest number of physicians in an area formally opposed the PSRO program, a physician group may be designated as an alternate PSRO. We believe that the opposition was likely to be the major reason for there being no priority PSRO in that area, without regard to when the opposition was registered.

REDESIGNATION

The proposed rule was designated as a new part 471. Final regulations on grants to PSRO's were published on July 24, 1978 (43 FR 32084), at 42 CFR Part 462. Those regulations contain the requirements for designation of priority PSRO's. It is appropriate that the requirements for designation of alternate PSRO's be in the same part. Accordingly we have redesignated the content of the proposed part 471 as § 462.5 of 42 CFR Part 462.

42 CFR Part 462 is amended by revising the table of contents, revising § 462.3 and deleting its footnote, and adding a new § 462.5, to read as follows:

PART 462—GRANTS TO PROFESSIONAL STANDARDS REVIEW ORGANIZATIONS

Sec.
462.1 Scope and applicability.
462.2 Definitions.
462.3 Eligibility for grants.
462.4 Requirements for designation as a priority PSRO.
462.5 Requirements for designation as an alternate PSRO.
462.6 Application requirements for conditional designation.
462.7 [Reserved]
462.8 Conditional designation as a PSRO.
462.9 [Reserved]
462.10 Limitation on period of conditional designation.
462.11 Duration, renewal and termination of grants.
462.12 Use of grant funds.
462.13 Publications and copyrights.
462.14 Applicability of 45 CFR Part 74.
462.15 Additional terms and conditions.

AUTHORITY: Secs. 1152, 1154, and 1155(f) (2) and (3), Social Security Act, 86 Stat. 1430, 1431, 1432, 1435 (42 U.S.C. 1320c-1, 1320c-3, 1320c-4(f) (2) and (3)); sec. 1102, Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

§ 462.3 Eligibility for grants.

The following two categories of organizations are eligible for grants under this part:

(a) Organizations that meet the requirements for priority PSRO's (see § 462.4); and

(b) Organizations that meet the requirements for alternate PSRO's. (See § 462.5.)

§ 462.5 Requirements for designation as an alternate PSRO.

(a) *Absence of priority organization.* (1) The Secretary may initially designate an alternate PSRO in an area only if there is no priority organization that meets the requirements of §§ 462.4 and 462.8.

(2) The Secretary will withdraw the designation of an alternate PSRO, by not renewing its grant, if: (i) An organization that meets the requirements for priority organizations applies and is qualified for designation as a PSRO; (ii) that organization has not previously been designated as a PSRO; and (iii) the Secretary anticipates that the designation of that organization will result in substantial improvement in the performance of PSRO duties.

(b) *Organizational requirements.* To be eligible for designation as an alternate PSRO, an organization must:

(1) Have, or show that it will be able to obtain, the services of individuals with medical expertise to perform review activities competently;

(2) Demostrate its ability to perform review within the boundaries of the designated area;

(3) Be an organization other than a medical society;

(4) Be free from excessive influence by a medical society in making decisions;

(5) Not reserve board of director positions for members of a medical society;

(6) Not be an organization composed exclusively of licensed doctors of medicine or osteopathy unless it is an existing PSRO for another area, or the medical society in the area has previously taken a clear position of opposition to, or noncooperation with, the PSRO program;

(7) Not have inherent conflicts of interest that affect its role as a reviewer of health care; and

(8) Be willing to perform PSRO activities without making a profit.

For purposes of this paragraph medical society means the physician organization representing the largest number of physicians or doctors of osteopathy in the PSRO area.

(c) *Evaluation.* Before designating an alternate PSRO, the Secretary will consider the degree of support the organization has from the health care institutions, health related organizations, health care practitioners and consumers in the PSRO area.

(d) *Priorities for consideration of applicants.* If more than one organization submits an application to be an alternate PSRO for a given area, the order of priority among those found to be equally qualified will be:

(1) Organizations (excluding carriers, fiscal intermediaries and other health insurers) that are physically located or headquartered in the PSRO area;

(2) Existing PSRO's;

(3) Organizations (excluding carriers, fiscal intermediaries and other health insurers) that are located outside the PSRO area, but within the State in which the PSRO area is located;

(4) Organizations (excluding carriers, fiscal intermediaries, and other health insurers) that are located outside the State in which the PSRO is located;

(5) Carriers, fiscal intermediaries and other health insurers.

Dated: September 25, 1978.

ROBERT A. DERZON,
Administrator.

Approved: September 27, 1978.

HALE CHAMPION,
Acting Secretary.

[FR Doc. 78-27643 Filed 9-28-78; 8:45 am]

[1505-01]

CHAPTER I—PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER D—GRANTS

PART 54a—GRANTS FOR ALCOHOL ABUSE AND ALCOHOLISM PREVENTION, TREATMENT, AND REHABILITATION SERVICES AND NATIONAL ALCOHOL RESEARCH CENTERS

Correction

In FR Doc. 78-25457, appearing at page 40386 in the issue for Monday, September 11, 1978, make the following corrections:

(1) On page 40388, in the first column, in the third full paragraph, in the fourth line, the word "Shows" should be deleted.

(2) Also on page 40388, in the middle column, under the center heading "ADVISORY COUNCIL MEMBERSHIP", in the first paragraph, in the 6th line, the word "require" should read "required".

(3) On page 40392, in the first column, in the authority citation for Subpart A, in the second line, delete the quotation marks around "and 4588."

(4) On page 40392, in § 54a.101, in the last line and in the fourth from last line, delete the quotation marks.

(5) On page 40393, in the middle column, in § 54a.203(a) the formula was incorrectly set and should read as follows:

$$\text{State allotment} = \text{Population of State} \times \frac{\text{Total funds appropriated}}{\text{Population of U.S.}} \times \left(\frac{1}{2} \frac{\text{Per capita income of U.S. (3-year average)}}{\text{Per capita income of State (3-year average)}} + \frac{1}{2} \frac{\text{Need in State}}{\text{Need in U.S.}} \right)$$

(6) Also on page 40393, in § 54a.203, paragraphs (b) and (c) are reprinted below to correct several typographical errors:

(b) In making the calculation specified in paragraph (a) of this section for Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands, the Secretary, in the absence of income data and estimates of need specific to these areas which are, in his judgment, satisfactory, will use the highest estimate of Need in State and the highest estimate of:

Per capita income of U.S. (3-year average)/ Per capita income of State (3-year average)

(c) In any fiscal year for which the amount appropriated under section 301 of the act is equal to or greater than the amount appropriated for the fiscal year ending June 30, 1976, if, after determining the amount of the allotment for each State in accordance with paragraph (a) of this section, it appears that any State (with the exception of the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands) will receive less than $200,000, the Secretary shall reduce the shares of each State which would receive more than $200,000 by an equal percentage and reallocate these sums as required to assure that every State (other than the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and the Northern Mariana Islands) will receive at least $200,000.

(7) On page 40396, in § 54a.210(c)(2), in the third line, insert "Abuse" between "Alcohol" and "Advisory".

(8) Also on page 40396, in § 54a.211(a)(2)(i), in the third line, "areas" should be corrected to read "area".

[4110-12]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE)

Conditions for Federal Financial Participation in the Cost of Automatic Data Processing

AGENCY: Department of Health, Education, and Welfare (HEW).

ACTION: Final rule.

SUMMARY: The regulation contains requirements for the claiming of Federal matching funds for the acquisition and use of automatic data processing (ADP) equipment and services in the administration of the financial assistance, medical assistance, social services, and child support enforcement programs under the Social Security Act.

EFFECTIVE DATE: This regulation is effective on December 28, 1978, or earlier at State option.

FOR FURTHER INFORMATION CONTACT:

L. David Taylor, 202-245-6162.

SUPPLEMENTARY INFORMATION: The regulation consolidates and codifies procedures for implementing the principles of OMB Circular A-90 and the provisions of 45 CFR Part 74, Appendix C, Part II, C. 1, pertaining to the claiming of Federal financial participation for the acquisition and use of automatic data processing equipment and services. This regulation is applicable to the financial assistance, medical assistance, social services, and child support enforcement programs under titles I, IV-A, IV-B, IV-C, IV-D, X, XIV, XVI (AABD), XIX, and XX of the Social Security Act.

45 CFR Part 74, Appendix C, Part II, C. 1, requires prior approval by grantor agencies for the costs of data processing equipment. OMB Circular A-90 requires that Federal agencies insure that systems development activities for which States are requesting Federal funding are well planned and do not involve duplication of effort and expense.

The regulation requires States, and local governments through States, to obtain prior approval from HEW of a written plan of action that contains a statement of needs and objectives, a preliminary cost/benefit analysis, a description of the scope and nature of the activities to be undertaken and the methods to be used to accomplish the activities, a proposed activity schedule, and an estimate of costs. In addition, the regulation requires prior approval for requests for proposals (RFP's) that States estimate to cost in excess of $25,000, permits HEW to require selectively prior approval of contracts that cost more than $25,000, and emphasizes the competitive procurement requirements in 45 CFT Part 74 Subpart P.

The regulation provides for subsequent HEW review of State and local agency acquired equipment and services to insure that they are used for the purpose for which Federal funds were approved.

The regulation is based on the provisions in sections 3, 403, 422, 433, 455, 1003, 1102, 1403, 1603, 1903, and 2002 of the Social Security Act; 45 CFT Part 74, Appendix C, Part II, C. 1; and OMB Circular A-90.

A notice of proposed rulemaking was published on February 24, 1976, in the FEDERAL REGISTER (41 FR 8065). The Department received comments from 15 State health and welfare departments. The comments suggested only minor changes to the proposed rulemaking. The specific comments and the Department's response are as follows:

1. *Comment:* The introductory statement on programs coverage does not agree with detailed statements in the text of this regulation.

Response: The preamble to the proposed rulemaking stated that "the program covered under this section are Federal-State programs of public assistance and medical assistance." The term "public assistance" is intended to cover the programs of cash assistance and services other than medical assistance. The preamble and 95.601 defines program coverage to include titles I, IV-A, IV-B, IV-C, IV-D, X, XIV, XVI (AABD), XIX, and XX of the Social Security Act.

2. *Comment:* Duplication or conflict between proposed 45 CFR Part 95, Subpart F and 42 CFR 450.90 (previously 45 CFR 250.90).

Response: The Health Care Financing Administration will revise 42 CFR 450.90 to incorporate a reference to this subpart and to eliminate any existing duplication. There is no conflict between these two regulations.

3. *Comment:* Reference to the Social and Rehabilitation Service as "Service" is sometimes confusing with the definition of services, an entirely different matter.

Response: The regulation is changed to use "Department" instead of "Service." Since the publication of the notice of proposed rulemaking, the Social and Rehabilitation Service (SRS) was abolished and the responsibility for SRS programs reassigned to the Social Security Administration (SSA) for cash assistance for titles I, IV-A, X, XIV, and XVI (AABD); Office of Human Development Services (OHDS) for Social Services for titles I, IV-A, IV-B, IV-C, X, XIV, XVI (AABD), and XX; and Health Care Financing Administration (HCFA) for title XIX. To minimize coordination problems caused by the reorganization, State ADP requests are addressed to the Assistant Secretary for Management and Budget (ASMB). That office forwards requests to the appropriate offices and is responsible for coordinating requests that involve more than one HEW component.

4. *Comment:* The regulation should include a statement that relates to other titles which might become involved, particularly titles II and XVIII.

Response: Titles II and XVIII are programs administered under a separate set of regulations.

5. *Comment:* The need to obtain an approved acceptance document will require the employment of additional staff.

Response: The Department recognizes that a State may need to augment its staff to plan and monitor projects that are subject to this regulation. We consider this a requirement for good management and expect that the responsible State agency will see that this necessary function is fulfilled.

6. *Comment:* The Department should require in the advance planning document (APD) a statement that specifies a period of time for which the systems described are to be used.

Response: The Department agrees with this comment. The definition for an APD is amended to add after the word "budget" the phrase "and a statement indicating the period of time for which the systems described are expected to be used."

7. *Comment:* The activities required to produce an APD are substantial and require the completion of studies related to project scope, feasibility, cost/benefit analysis, project plan, and budget. It is assumed that these activities do qualify for FFP and that the exemption of services that do not exceed $25,000 allows the use of ADP services in the development of the APD.

Response: Such activities do qualify for FFP at the appropriate rate, and HEW prior approval is not required if the expenditures for each study do not exceed $25,000.

8. *Comment:* The definition of ADP services appears to include services provided by State agency staff, and implies that States need prior approval for agency developed systems and ongoing maintenance.

Response: HEW requires prior approval of State agency developed systems that cost in excess of $25,000. HEW does not require separate approval of ongoing maintenance provided the system request includes the cost of ongoing maintenance.

9. *Comment:* A question was raised of the desirability of applying the proposed regulation to those situations where ADP services are provided by a State central data processing facility to other State agencies.

Response: The regulation requires that an agreement be signed by both the providing and receiving agencies when services are obtained from a central source. The purpose of this requirement is to assure that services are provided with sufficient quality at an equitable rate and that both parties are fully aware of their individual responsibilities. The Department has required such agreements since 1965.

10. *Comment:* Provider should be defined so as to exempt a State central data processing facility operating as a service center that earns (cash funds) from the requirement for prior approval.

Response: A State central data processing facility must comply with the prior approval requirements when it provides ADP services to the State agency that exceed $25,000. Specifically § 95.613 requires prior HEW approval of equipment that is acquired by the State central data processing facility primarily to support the programs covered by the regulation, and § 95.611(b) requires prior approval of the service agreement between the State agency and State central data processing facility.

11. *Comment:* "Software" and "documentation" are not necessarily the same and should be clarified.

Response: Documentation as used in definition for "software" means the detailed specification (program specification, standards, construction, coding, testing, and program management) and description of the software computer programs.

12. *Comment:* The regulation should make it clear that the proposed amount of $25,000 applies only to programs under the responsibility of HEW and that amounts under $25,000 are not subject to the Federal approval process.

Response: Section 95.601(a) specifies titles I, IV-A, IV-B, IV-C, IV-D, X, XIV, XVI (AABD), XIX, and XX of the Social Security Act as the programs covered by this regulation. System developments or hardware acquisitions in support of other Federal programs are not subject to the requirements of this regulation. Procurements under $25,000, while not subject to prior approval, are subject to periodic review.

13. *Comment:* Does the exemption from prior approval cited in § 95.623 extend to all subitems in § 95.611(b) (1) through (5).

Response: The exemption applies to all subitems listed in § 95.611(b) (1) through (5).

14. *Comment:* What are the criteria for ascertaining when a modification or task in systems maintenance requires prior approval?

Response: Any system modification that increases the contract or service agreement by more than $25,000 requires prior approval. The cost of ongoing maintenance for approved ADP services is an identified charge in the contract or State service agreement; accordingly, HEW does not require separate approval of ongoing maintenance. If the State agency requests a contractor or State central data processing facility to provide additional ADP services, including system modification or maintenance support, that cost $25,000 more than charges covered in the contract or service agreement, then HEW requires prior approval for the additional ADP services.

15. *Comment:* The $10,000 baseline is low and should be increased to $25,000. It is not clear if the baseline amount applies separately to equipment and services or to the aggregate.

Response: The $10,000 baseline is increased to $25,000. This baseline applies to individual acquisitions of equipment or services.

16. *Comment:* The regulation should exclude ADP services to handle federally supplied data such as buy-in, Bendex, social security enumeration, and SSI data. Prior approval of administrative expenses will impede development of effective systems.

Response: Normally, system development changes of this type would not exceed a cost of $25,000 and would not require prior approval. When such efforts do exceed the $25,000 limit, prior approval is required.

17. *Comment:* It is assumed that changes are exempt from the prior approval requirement if the major system itself was implemented in conformance with these provisions.

Response: Any system modification or enhancement that exceeds $25,000 requires prior departmental approval.

18. *Comment:* The conventional keypunch service should be further defined.

Response: To clarify the regulation the definition for conventional keypunch services is eliminated and a definition is added for data input equipment. The definition includes, but is not limited to, the following types of data input equipment: Punchcard accounting machines, keypunch, key to disk, key to magnetic tape, optical character recognition, hardcopy and video display terminals, and word processing equipment primarily used to input data.

19. *Comment:* What does the $25,000 include? Total system cost? Cost per system component, etc.?

Response: The $25,000 limit applies to individual acquisitions of ADP equipment or services for the estimated or actual period of time covered by the advance planning document, RFP, contract, or service agreement. Guidelines for periodic HEW review of acquisitions of $25,000 or less will insure that several small acquisitions are not used as a substitute for a single acquisition in excess of $25,000.

20. *Comment:* HEW should limit prior approval to new applications with routine maintenance provided by a State central data processing facility explicitly exempted from prior approval provisions.

Response: Prior approval is not required unless a new individual acquisition or development task exceeds $25,000. The response to comment 14 addresses routine maintenance.

21. *Comment:* The Department should permit telephone clarification of minor technical points. The APD is a basic planning document and should not be regarded as a final design product.

Response: The Department recognizes that the APD is the initial step to a system development effort and may require amendments. The supporting guidelines to this regulation

encourage the use of the telephone to clarify minor technical points; such clarification will be confirmed in writing.

22. *Comment:* The addition of the exception provided for in § 95.613 is a good one and it is realistic. The sentence in question is: "The service agreement between the State agency and the State central data processing facility is exempt from the procurement standards." This exception had not been previously provided for in 45 CFR 74.155.

Response: This provision was added because the procurement standards in subpart P of 45 CFR Part 74 do not require that State and local government agencies compete with the private sector.

23. *Comment:* Section 95.613 does not acknowledge the complexity of State procurement policy. Most States have a local centralized ADP procurement authority which limits the possibility of strict adherences to competitive bidding. A nonindustrial State finds it very difficult to locate after-the-sale service, and approach the problem through life cycle costing which includes system maintenance.

Response: The procurement standards in 45 CFR part 74, subpart P, provide States the option to use competitive negotiation if formal advertising is not practical or feasible, but under either method of procurement, States must specify all requirements needed for an acceptable bid. Where there is only one supplier of ADP equipment or services, sole source procurement may be justified.

24. *Comment:* HEW should amend the regulation to say that when sufficient justification exists to replace an ADP system prior to the time delineated in the "Advance Planning Document," the use of the system may be terminated without penalty.

Response: The final clause of § 95.619 states "* * * unless the Department determines that an elapsed shorter period of time is sufficient to justify the Federal funds invested." This paragraph provides HEW with the option to permit termination of a system in a time period shorter than originally stated in the APD when sufficiently justified.

25. *Comment:* The Department should conduct periodic onsite reviews so as to avoid disruption and assure that the appropriate staff are available.

Response: Section 95.621 now states that "where practical, the Department will develop a mutually acceptable schedule between the Department and State or local agencies prior to conducting onsite surveys and reviews."

26. *Comment:* Section 95.631 appears to invalidate previously approved cost allocation plans.

Response: The ADP equipment and services approved under § 95.611 may cause the State to change the ADP billing rates or billing methods in the approved cost allocation plan. The relationship between subpart F and the cost allocation plan is explained in § 95.631.

27. *Comment:* A recommendation was made that automatic approval be granted when the Department fails to respond to a State request within 60 days.

Response: HEW cannot grant automatic approval because the submittal may fail to meet the requirements of Federal laws and regulations. State requests that meet requirements will normally be approved in 30 days. If HEW has not communicated approval or disapproval within 30 days, the ASMB or a HEW component will notify the State regarding the status of the request for prior approval.

28. *Comment:* The regulation should specify that this approval authority relates to the technical merit of a system and not to the program policy aspects.

Response: Approvals are based on improvements in program support and the technical merits of the request. In addition, the request must comply with program policy.

29. *Comment:* The regulation should specify who has the final approval authority. In the past we have identified up to five central offices who thought they were the approval authority.

Response: Offices with authority for prior approvals required as a condition for FFP are specified in the regulation. The ASMB coordinates an HEW reply for requests that involve more than one HEW component. Requests that involve a single component are answered by that component.

Other changes made in response to review within HEW included:

1. Word order changes to make clear that matching rates are not set by the State plan (§ 95.601).

2. New subdivisions (e) and (f) to the definition of service agreement make clear that existing requirements are applicable to agreements with providers of ADP services.

3. A definition of "Department" is added.

4. A definition of "approving component" is added.

5. A definition of "State agency" is added.

6. Section 95.611 is reworded to clarify when and for what prior approval is required.

7. Editorial changes are made in § 95.615.

8. Section 95.619 is revised to clarify the time relationships.

9. Section 95.631 caption is changed to read "Relationship to the approved cost allocation plan."

10. Clarifying language is added to § 95.623.

11. The title of § 95.611(c) is made more specific.

12. A new § 95.641 specifies that the capitalization and depreciation provisions of 45 CFR 205.160(a) and 304.24 do not apply to ADP equipment provided the purchase benefits the Department and provided the Department agrees to the ADP equipment purchase. The purchase of ADP equipment is beneficial when HEW saves money as a result of the purchase.

13. A new § 95.643 is added to exempt ADP equipment and services that cost $25,000 or less from the requirement for prior approval.

14. The notice of proposed rulemaking was published under 45 CFR 204.6. As part of HEW's recodification effort the final regulation is published under 45 CFR Part 95, Subpart F.

The proposed regulation, with the changes discussed above, is hereby adopted.

(Catalog of Federal Domestic Assistance Program Nos. 13.679, Child Support Enforcement Program; 13.707, Child Welfare Services; 13.714, Medical Assistance Program; 13.724, Public Assistance State and Local Training; 13.748, Work Incentive Program—Child Care—Employment Related Supportive Services; 13.754, Public Assistance—Social Services; 13.761, Public Assistance—Maintenance Assistance (State Aid); 13.771, Social Services for Low Income and Public Assistance.)

NOTE.—The Department has determined that this document does not require preparation of an economic impact statement under Executive Order 11821 and 11949 and OMB Circular A-107.

Dated: May 12, 1978.

ROBERT A. DERZON,
Administrator, Health Care Financing Administration.

ARABELLA MARTINEZ,
Assistant Secretary for Human Development Services.

FRANCIS D. DEGEORGE,
Acting Commissioner, Social Security.

LOUIS B. HAYS,
Acting Director, Office of Child Support Enforcement.

Approved: August 28, 1978.

HALE CHAMPION,
Acting Secretary.

1. Part 95, Subtitle A, Title 45 of the Code of Federal Regulations is amended by establishing a new part 95 to read as follows:

PART 95—GENERAL ADMINISTRATION—GRANT PROGRAMS (PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE)

Subpart A—[Reserved]
Subpart B—[Reserved]

Subpart C—[Reserved]
Subpart D—[Reserved]
Subpart E—[Reserved]
Subpart F—Automatic data processing equipment and services—conditions for Federal financial participation

GENERAL

Sec.
95.601 Scope and applicability.
95.605 Definitions.

SPECIFIC CONDITIONS FOR FFP

95.611 Prior approval conditions.
95.613 Procurement standards.
95.615 Access to records.
95.617 Software ownership rights.
95.619 Use of ADP systems.
95.621 ADP reviews.
95.623 Waiver of prior approval requirements.

COST ALLOCATION PLAN

95.631 Relationship to the approved cost allocation plan.

EXEMPTIONS

95.641 Exemption from 45 CFR 205.160(a) and 304.24.
95.643 Exemption from 45 CFR Part 74, Appendix C, Part II C.1.

AUTHORITY: Sec. 1102, 49 Stat. 647, 42 U.S.C. 1302; sec. 7(b) 68 Stat. 658, 29 U.S.C. 37(b); sec. 139, 84 Stat. 1323, 42 U.S.C. 2577b; sec. 144, 81 Stat. 529, 42 U.S.C. 2678.

Subpart F—Automatic Data Processing Equipment and Services—Conditions for Federal Financial Participation

GENERAL

§ 95.601 Scope and applicability.

This subpart prescribes the conditions under which the Department of Health, Education, and Welfare will approve Federal financial participation (FFP), at the applicable rates, for the costs of automatic data processing incurred under an approved State plan for titles I, IV-A, IV-B, IV-C, IV-D, X XIV, XVI (AABD), XIX, or XX of the Social Security Act.

§ 95.605 Definitions.

"Acceptance documents" means written evidence of satisfactory completion of an approved phase of work or contract, and acceptance thereof by the State agency.

"Advance planning document" or "APD" means a written plan of action to acquire the proposed ADP services or equipment. The APD must contain a statement of needs and objectives; a preliminary cost/benefits analysis; a personnel resource statement indicating availability of qualified and adequate staff, including a project director to accomplish the project objectives; a detailed description of the nature and scope of the activities to be undertaken and the methods to be used to accomplish the project; a proposed activity schedule for the project; a proposed budget; and a statement indicating the period of time the State expects to use the ADP service or equipment.

"Approving component" means an organization within the Department that is authorized to approve requests for the acquisition of ADP equipment or ADP services that exceed $25,000 in Federal and State funds; Social Security Administration (SSA) for cash assistance for titles I, IV-A, X, XIV, and XVI (AABD); Office of Human Development services (OHDS) for social services for titles I, IV-A, IV-B, IV-C, X, XIV, XVI (AABD), and XX; Office of Child Support Enforcement (OCSE) for title IV-D; and Health Care Financing Administration (HCFA) for title XIX of the Social Security Act.

"Automatic data processing" or "ADP" means data processing performed by a system of electronic or electrical machines so interconnected and interacting as to minimize the need for human assistance or intervention.

"Automatic data processing equipment" or "ADP equipment" means:

(a) Electronic digital computers, regardless of size, capacity, or price, that accept data input, store data, perform calculations, and other processing steps and prepare information output;

(b) All peripheral or auxiliary equipment used in support of electronic computers whether selected and acquired with the computer or separately;

(c) Data transmission or communications equipment that is selected and acquired solely or primarily for use with a configuration of ADP equipment which includes an electronic computer and;

(d) Data input equipment that is used to enter data directly or indirectly into an electronic digital computer; peripheral or auxiliary equipment; or data transmission or communications equipment.

"Automatic data processing services" or "ADP services" means:

(a) Services to operate ADP equipment, either by private sources, or by employees of the State agency, or by State or local organizations other than the State agency; and/or

(b) Services provided by private sources or by employees of the State agency or by State and local organizations other than the State agency to perform such tasks as feasibility studies, system studies, system design efforts, development of system specifications, system analysis, programing and system implementation.

"Data processing" means the preparation of source media containing data or basic elements of information, and the use of such source media according to precise rules of procedures to accomplish such operations as classifying, sorting, calculating, summarizing, recording, and transmitting.

"Department" means the Department of Health, Education, and Welfare.

"Feasibility study" means a preliminary study to determine whether it is sufficiently probable that effective and efficient use of ADP equipment or systems can be made to warrant the substantial investment of staff, time, and money.

"FFP" means Federal financial participation.

"Service agreement" means a document signed by the State or local agency and the State or local central data processing facility providing ADP services (provider) which;

(a) Identifies those ADP services the central data processing facility will provide;

(b) Includes, preferably as an amendable attachment, a schedule of charges for each identified ADP service, and a certification that these charger apply equally to all users;

(c) Includes a description of the method(s) of accounting for the services rendered under the agreement and computing services charges;

(d) Includes assurances that services provided will be timely and satisfactory;

(e) Includes assurances that information in the computer system as well as access, use, and disposal of ADP data will be safeguarded in accordance with provistons of 45 CFR 205.50 and 45 CFR 302.18; and

(f) Includes a clause that prohibits the provider from discriminating against employees on the basis of their race, sex, religion, and age.

(g) Requires the provider to obtain prior approval from the Department for ADP equipment and ADP services that is acquired primarily to support the titles covered by this subpart and requires the provider to comply with 45 CFR Part 74, Subpart P for procurements related to the service agreement.

"Software" means a set of computer programs, procedures, and associated documentation by which ADP equipment is used and operated.

"State agency" means the State agency administering or supervising the administration of the State plan that is required by the Department for the Social Security Act programs.

"System design" means the putting together of a new or more efficient ADP system.

"System specifications" means information about the new ADP system—such as workload descriptions, input data, information to be maintained and processed, data processing techniques, and output data—which is re-

quired to determine the ADP equipment and software necessary to implement the system design.

"System study" means the examination of existing information flow and operational procedures within an organization. The study essentially consists of three basic phases: data gathering, investigation of the present system and new information requirements; analysis of the data gathered in the investigation; and synthesis, or refitting of the parts and relationships uncovered through the analysis into an efficient system.

SPECIFIC CONDITIONS FOR FFP

§ 95.611 Prior approval conditions.

(a) *General—$25,000 acquisition requirement.* A State must obtain prior written approval by the Department for acquisition of ADP equipment or ADP services when the acquisition cost of ADP equipment or ADP services exceeds $25,000 in Federal and State funds. The State shall submit requests for prior systems approval, signed by the appropriate State official, to the Assistant Secretary for Management and Budget (ASMB), Department of Health, Education, and Welfare. Requests from States shall indicate clearly the Social Security Act titles under which funding is requested, and the estimated amount or percent that is requested for each title. The State shall send three copies of the request for each component to the Department that must approve the request. The Department will acknowledge receipt of the State request.

(b) *Specific prior approval requirements.* The State agency shall obtain written approval of the Department:

(1) For the advance planning document or any change of the advance planning document prior to entering into contractual agreements or making any other commitment for acquisition of ADP equipment or ADP servces;

(2) For the service agreement (when data processing services are to be provided by a State central data processing facility or by another State or local agency);

(3) For the request for proposal (RFP), prior to its issuance when service or equipment proposals are being solicited from commercial sources;

(4) When required, for the contract, prior to signature of the contracting officer. The Department requires approval of the contract for complex procurements, or where the grantee has a history of performance problems.

(5) When required for:

(i) The feasibility study;

(ii) The system study;

(iii) The system design;

(iv) The system specifications; and

(v) The acceptance document.

The Department will notify the State agency if such prior approval is required under paragraphs 95.611(b)(4) or (5).

(c) *Prompt action on requests for prior approval.* The ASMB will promptly send to the approving components the items specified in paragraph (b) of this section. If the Department has not communicated approval or disapproval within 30 days the ASMB or an approving component will notify the State regarding the status of the request.

§ 95.613 Procurement standards.

Procurements of ADP equipment and services are subject to the procurement standards in subpart P, 45 CFR, part 74. Those standards include a requirement for maximum practical open and free competition regardless of whether the procurement is formally advertised or negotiated. Those standards, as well as the requirement for prior approval, apply to ADP services and equipment acquired by a State or local agency, and to ADP services and equipment acquired by a State or local central data processing facility primarily to support the Social Security Act programs covered by this subpart. The service agreement between the State agency and the State central data processing facility is exempt from the procurement standards because State and local government gencies are not required to compete with the private sector.

§ 95.615 Access to records.

In accordance with 45 CFR Part 74, Subpart D, the State agency must allow the Department access to the system in all of its aspects, including design developments, operation, and cost records of contractors and subcontractors at such intervals as are deemed necessary by the Department to determine whether the conditions for approval are being met and to determine the efficiency, economy and effectiveness of the system.

§ 95.617 Software and ownership rights.

(a) *General.* The State or local government will have all ownership rights in software or modifications thereof and associated documentation designed, developed or installed with Federal financial participation under this subpart.

(b) *Exemption.* The Department reserves a royalty-free—nonexclusive and irrevocable license to reproduce, publish, or otherwise use, and to authorize others to do so, such software, modification and documentation.

(c) *Proprietary software.* Proprietary software which is provided at established catalog or market prices and sold or leased to the general public shall not be subject to the ownership provisions of this subpart.

§ 95.619 Use of ADP systems.

ADP systems designed, developed, or installed with Federal financial participation shall be used for a period of time specified in the ADP, unless the Department determines that the elapsed shorter period of time is sufficient to justify the Federal funds invested.

§ 95.621. ADP reviews.

The Department will conduct periodic onsite surveys and reviews of State and local agency ADP methods and practices to determine the adequacy of such methods and practices and to assure that ADP equipment and services are utilized for the purposes consistent with proper and efficient administration under the Act. Where practical, the Department will develop a mutually acceptable schedule between the Department and State or local agencies prior to conducting such surveys or reviews, which may include but are not limited to:

(a) *Pre-installation readiness.* A pre-installation survey including an onsite evaluation of the physical site and the agency's readiness to productively use the proposed ADP services, equipment or system when installed and operational.

(b) *Post-installation.* A review conducted after installation of ADP equipment or systems to assure that the objectives for which FFP was approved are being accomplished.

(c) *Utilization.* A continuing review of ADP facilities to determine whether or not the ADP equipment or services are being efficiently utilized in support of approved programs or projects.

§ 95.623 Waiver of prior approval requirements.

ADP equipment and services acquired by a State agency prior to the effective date of these regulations may qualify for FFP provided the Department waives the prior approval requirement. The Department will waive the prior approval requirement when it determines that the ADP equipment or services would have received prior approval had a request for such approval been made by the State agency.

COST ALLOCATION PLAN

§ 95.631 Relationship to the approved cost allocation plan.

(a) *General.* The conditions of this subpart apply notwithstanding the existence of an approved cost allocation plan. States that operate with a central data processing facility shall use the approved cost allocation plan billing rates and billing methods in the service agreement with the State

agency. The State shall bill the Department, at the approved rates, for the ADP equipment and services used by the individual Department programs.

(b) *Impact on the cost allocation plan.* ADP equipment and services purchased or leased by the State central data processing facility may cause a change to the approved cost allocation plan. (For example, the lease of an additional nondedicated computer.) When a change is necessary, the State shall revise the billing rates and billing methods prior to revising the service agreement.

EXEMPTIONS

§ 95.641 Exemption from 45 CFR 205.160(a) and 304.24.

The capitalization and depreciation provisions of 45 CFR 205.160(a) and 304.24 do not apply to ADP equipment provided the purchase benefits the Department and provided the Department agrees to the ADP equipment purchase.

§ 95.643 Exemption from 45 CFR Part 74, Appendix C, Part II, C.1.

The requirment in 45 CFR Part 74, Appendix C, Part II, C.1. for prior approval of ADP equipment and services is waived for items that cost $25,000 or less.

[FR Doc. 78-27290 Filed 9-28-78; 8:45 am]

[4310-55]

Title 50—Wildlife and Fisheries

CHAPTER I—UNITED STATES FISH AND WILDLIFE SERVICE DEPARTMENT OF THE INTERIOR

PART 32—HUNTING

Opening of the Oxbow National Wildlife Refuge, Mass., To Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulation.

SUMMARY: The Director has determined that the opening to hunting of Oxbow National Wildlife Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public.

DATES: October 1, 1978, through January 31, 1979.

FOR FURTHER INFORMATION CONTACT:

David Beall, Great Meadows National Wildlife Refuge, 191 Sudbury Road, Concord, Mass. 01742, telephone No. 617-369-5518.

SUPPLEMENTARY INFORMATION:

§ 32.12 Special regulations; migratory game birds, for individual wildlife refuge areas.

Public hunting of woodcock and snipe on the Oxbow National Wildlife Refuge, Mass., is permitted on the area designated by signs as open to hunting.

§ 32.22 Special regulations; upland game; for individual wildlife refuge areas.

Public hunting of upland birds and small game on the Oxbow National Wildlife Refuge, Mass., is permitted on the area designated by signs as open to hunting.

These open areas, comprising 600 acres, are shown on maps available at refuge headquarters, Concord, Mass., or from the Regional Director, U.S. Fish and Wildlife Service, 1 Gateway Center, Suite 700, Newton Corner, Mass. 02158. Hunting shall be in accordance with all applicable State and Federal regulations covering the hunting of migratory game birds and upland game, subject to the following special conditions:

(1) The total number of hunters on the area will be limited to fifty (50) hunters at one time.

(2) Permits will be required daily.

(3) Hunters must check in, obtain a permit, and check out at the Fort Devens Rod and Gun Club each day.

(4) Vehicles are restricted to designated parking areas.

The provisions of this special regulation supplemental the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

Administrative needs require that Oxbow Refuge hunting season be held concurrent with the Massachusetts State hunting season. It is therefore found impracticable to issue regulations that would be effective 30 days after publication in accordance with Department of the Interior general policy.

NOTE.—The U.S. Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

HOWARD N. LARSEN,
Regional Director,
U.S. Fish and Wildlife Service.

SEPTEMBER 21, 1978.

[FR Doc. 78-27438 Filed 9-28-78; 8:45 am]

[4310-55]

PART 32—HUNTING

Opening of the Montezuma National Wildlife Refuge, N.Y., To Hunting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special regulation.

SUMMARY: The Director has determined that the opening to hunting of Montezuma National Wildlife Refuge is compatible with the objectives for which the area was established, will utilize a renewable natural resource, and will provide additional recreational opportunity to the public.

DATES: October 1, 1978, through February 28, 1979.

FOR FURTHER INFORMATION CONTACT:

Gene Hocutt, Montezuma National Wildlife Refuge, R.D. 1, Box 1411, Seneca Falls, N.Y. 13148, telephone No. 315-568-5987.

SUPPLEMENTARY INFORMATION:

§ 32.12 Special regulations; migratory game birds; for individual wildlife refuge areas.

Public hunting of migratory waterfowl on the Montezuma National Wildlife Refuge, N.Y., is permitted from October 1, 1978, through December 31, 1978, on the areas designated by signs as open to waterfowl hunting. The waterfowl hunting area known as the Tschache Pool comprises 1,340 acres.

Hunting shall be in accordance with all State and Federal regulations covering the hunting of migratory waterfowl subject to the following special conditions:

1. Hunting is permitted on Tuesdays, Thursdays, and Saturdays.

2. Steel shot shells will be used for all waterfowl hunting. Hunters will be limited to 15 steel shot shells each, with shot size no larger than No. 1 fine shot. No person shall have lead shot in his possession during the hunt.

3. Applications for hunting reservations must be received no later than 2 weeks before the opening date of the waterfowl season. Reservations for permits will be selected by random drawing. Hunting will be allowed on the designated days from the opening of the State season to the end of the first part of a split season or until the third Saturday in November—whichever comes first. Successful applicants must appear in person at the refuge waterfowl check station prior to 1 hour before legal shooting time on the date reserved. Unreserved and forfeited permits will be awarded by a drawing on the morning of the hunt to hunters without reservations.

4. The first two Saturdays of the season will be reserved for the young waterfowler's training program hunt. A brochure describing this program is also available.

5. A person with reservation may bring no more than one companion.

6. All hunting ends each hunting day at 12 noon local time, and all hunters must check out at the waterfowl check station no later than 1 p.m. local time.

7. Successful completion of the New York State waterfowl identification course is required to hunt on the refuge.

8. Hunters when requested by Federal or State enforcement officers, must display for inspection all game, hunting equipment, and ammunition.

Administrative needs require that Montezuma Refuge migratory game bird season be held concurrent with the New York State hunting season. It is therefore found inpracticable to issue regulations that would be effective 30 days after publication in accordance with Department of the Interior general policy.

§ 32.22 **Special regulations; upland game; for individual wildlife refuge areas.**

The public hunting of gray squirrels, cottontail rabbits, raccoons, foxes, and unprotected mammals is permitted from December 17, 1978, through February 28, 1979, on the Montezuma National Wildlife Refuge, N.Y., except on areas designated by signs as closed.

A permit is required for night hunting of raccoon.

Hunting shall be in accordance with all State regulations governing the hunting of above mammals.

§ 32.32 **Special regulations; big game; for individual wildlife refuge areas.**

Public hunting of deer on the Montezuma National Wildlife Refuge, N.Y., is permitted from November 20, 1978, through December 12, 1978, except on the areas designated by signs as closed.

Hunting shall be in accordance with all State regulations covering the hunting of deer subject to the following special conditions:

1. Archery deer hunting is permitted Monday through Friday during the firearm season selected by the State.

2. Only longbows and compound bows may be used. No gun hunting will be allowed.

3. A deer of either sex may be taken.

4. Successful hunters must register their kill at refuge headquarters.

All hunting area maps are available at refuge headquarters and from the Regional Director, 1 Gateway Center, Suite 700, Newton Corner, Mass. 02158.

The provisions of these special regulations supplement the regulations which govern hunting on wildlife refuge areas generally, which are set forth in Title 50, Code of Federal Regulations, Part 32. The public is invited to offer suggestions and comments at any time.

NOTE.—The U.S. Fish and Wildlife Service has determined that this document does not contain a major proposal requiring preparation of an economic impact statement under Executive Order 11949 and OMB Circular A-107.

HOWARD N. LARSEN,
Regional Director,
U.S. Fish and Wildlife Service.

SEPTEMBER 21, 1978.

[FR Doc. 78-27439 Filed 9-28-78; 8:45 am]

[4310-55]

PART 32—HUNTING

Opening of Certain National Wildlife Refuges in Nevada to Hunting; Correction

AGENCY: U.S. Fish and Wildlife Service, Sacramento Area Office.

ACTION: Special regulations; correction.

SUMMARY: This notice amends a special regulation for migratory game bird hunting on certain wildlife refuges in Nevada (published at 43 FR 32304, July 26, 1978) to correct an omission.

EFFECTIVE DATE: October 7, 1978 through June 30, 1979.

FOR FURTHER INFORMATION CONTACT:

Patrick L. O'Halloran, Sacramento Area Office; telephone FTS 468-4771, com'l 916-484-4771.

SUPPLEMENTARY INFORMATION: FR Doc. 78-20621 appearing at page 32304 is corrected as follows:

Section 32.12, *Special regulations; migratory game birds; for individual wildlife refuge areas,* is corrected by the insertion of "Stillwater Wildlife Management Area, P.O. Box 1236, Fallon, Nev. 89406, telephone 702-423-5128" between the entries for Fallon and Paharanagat National Wildlife Refuges.

Dated: September 19, 1978.

WILLIAM D. SWEENEY,
Area Manager—California-Nevada,
U.S. Fish and Wildlife Service.

[FR Doc. 78-27630 Filed 9-28-78; 8:45 am]

[3510-22]

CHAPTER II—NATIONAL MARINE FISHERIES SERVICE, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 258—FISHERMEN'S PROTECTIVE ACT PROCEDURES

Provision for Fees

AGENCY: National Marine Fisheries Service, National Oceanic and Atmospheric Administration.

ACTION: Amendment of regulations.

SUMMARY: Section 7 of the Fishermen's Protective Act, as amended (22 U.S.C. 1971-1977), authorizes, among other things, the Secretary of Commerce to establish by regulation fees which shall be paid by the owners of vessels entering into guarantee agreements under section 7 of the Act. These fees established annually are credited to the Fishermen's Guarantee Fund and used to carry out the provisions of section 7 of the Act. This amendment establishes fees for the agreement year October 1, 1978, through September 30, 1979.

EFFECTIVE DATE: October 1, 1978.

ADDRESS: Financial Services Division, F25, National Marine Fisheries Service, Washington, D.C. 20235.

FOR FURTHER INFORMATION CONTACT:

Michael L. Grable, Chief, Financial Services Division, F25, National Marine Fisheries Service, Washington, D.C. 20235, 202-634-7496.

SUPPLEMENTARY INFORMATION: Section 7 of the Act guarantees to owners of vessels entering into guarantee agreements payment of certain costs and losses resulting from (1) the seizure of a vessel of the United States by a foreign country on the basis of rights or claims in territorial waters or the high seas which are not recognized by the United States, or (2) if recognized by the United States, (a) are unrelated to fishery conservation and management, (b) fail to consider traditional fishing practices of U.S. vessels, (c) are more onerous than those which the United States applies to foreign fishing vessels in U.S. fishery conservation zone, or (d) fail to allow U.S. fishing vessels equitable access to such country's fishery conservation zone.

Regulations governing administration of section 7 of the Act, Fishermen's Protective Act Procedures (50 CFR Part 258), have annually established fees based on anticipated claims and prior experience. The purpose of

the following amendment § 258.5 of Fishermen's Protective Act Procedures is to establish fees for the agreement year October 1, 1978, through September 30, 1979.

All parties holding guarantee agreements for the present agreement year (October 1, 1977, through September 30, 1978) who wish them extended through September 30, 1979, by amendment to such agreement, rather than entering into an entirely new agreement, must submit their fees in accordance with § 258.5(b) of the following amendment. Failure to do so will result in the termination of those agreements.

This amendment relates to matters which are exempt from the rulemaking requirements of the Administrative Procedures Act (5 U.S.C. 553). In addition, the amendment makes no substantive change in the program's conduct. The amendment follows.

Section 258.5 of Fishermen's Protective Act Procedures (50 CFR Part 258) is hereby amended by revising § 258.5 as follows:

§ 258.5 Fees.

(a) The fees are established to provide for payment of the administrative costs and a minimum of at least 25 percent of the estimated claims to be paid from the fund. They are set on the basis of anticipated losses and prior experience. In order to meet the requirements of the Act, the fees may be adjusted from time to time by amendment to this part at any time, after appropriate notice, to become consistent with claims greater or lesser than estimated.

(b) Fees to be paid by an applicant for guarantee agreements for the agreement year October 1, 1978, through September 30, 1979, shall be as follows: For each vessel $60, plus $1.62 per gross ton, as listed on the vessel's document. Fractions of a ton shall not be included. Although fees are due on October 1, 1978, all parties holding guarantee agreements (by amendment or otherwise) for the period terminating September 30, 1978, shall have until December 1, 1978 (midnight local time), to pay the fees established herein. Failure to do so will result in the necessity of entering into a new guarantee agreement which will be effective only from the date actually executed.

(c) No return of a fee or portion of a fee will be made after a guarantee agreement is executed by the Secretary.

(d) A guarantee agreement may, with consent of the Secretary, be assigned to a new owner of a vessel if the ownership of the vessel is transferred during the period in which the agreement is in force.

Dated: September 26, 1978.

JACK W. GEHRINGER,
Acting Deputy Assistant Administrator for Fisheries.

[FR Doc. 78-27450 Filed 9-28-78; 8:45 am]

[3410-34]

Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 73—SCABIES IN CATTLE

Area Quarantined

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The purpose of this amendment is to quarantine a portion of Johnson County in Kansas because of the existence of cattle scabies. A portion of one building on the Stanley Farm Facility of the Bayvet Division of Cutter Laboratories is being used to perform scabies research. The company will be using scabies infected animals for their study. Therefore, in order to prevent the dissemination of cattle scabies it is necessary to quarantine the area being used for research.

EFFECTIVE DATE: September 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. Glen O. Schubert, Chief Staff Veterinarian, Sheep, Goat, Equine, and Ectoparasites Staff, USDA, APHIS, VS, Federal Building, Room 737, 6505 Belcrest Road, Hyattsville, Md. 20782, 301-436-8322.

SUPPLEMENTARY INFORMATION: This amendment quarantines a portion of Johnson County in Kansas because of the existence of cattle scabies. The restrictions pertaining to the interstate movement of cattle from quarantined areas as contained in 9 CFR Part 73, as amended, will apply to the area quarantined.

Accordingly, Part 73, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of cattle because of scabies, is hereby amended as follows:

In § 73.1a, in paragraph (d) relating to the State of Kansas a new paragraph (6) relating to Johnson County is added to read:

§ 73.1a Notice of quarantine.

* * * * *

(d) * * *

(6) The east 168 feet of building No. 1 situated on the southwest corner of the northwest ¼ of sec. 29, T. 14, R. 25, known as the Stanley Research Farm, located approximately 3 miles south of Stanley, Kans., in Johnson County.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; secs. 3 and 11, 76 Stat. 130, 132 (21 U.S.C. 111-113, 115, 117, 120, 121, 123-126, 134b, 134f); 37 FR 28464, 28477; 38 FR 19141.)

The amendment imposes certain further restrictions necessary to prevent the interstate spread of cattle scabies and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendment are impracticable and contrary to the public interest, and good cause is found for making the amendment effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 22d day of September 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an inflation impact statement under Executive Order 11821 and OMB Circular A-107.

PIERRE A. CHALOUX,
Deputy Administrator, Veterinary Services.

[FR Doc. 78-27312 Filed 9-28-78; 8:45 am]

[3410-34]

SUBCHAPTER D—EXPORTATION AND IMPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 92—IMPORTATION OF CERTAIN ANIMALS AND POULTRY AND CERTAIN ANIMAL AND POULTRY PRODUCTS; INSPECTION AND OTHER REQUIREMENTS FOR CERTAIN MEANS OF CONVEYANCE AND SHIPPING CONTAINERS THEREON

Importation of Birds—Procedures for the Recovery of Costs of Services

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: This document establishes procedures for the recovery of costs of services provided by Veterinary Services in conjunction with the importation of birds through approved quarantine facilities. This action is necessary in order to place in effect a practical method of collection and deposit of such funds in a manner whereby they will be available to Veterinary Services for defraying expenses involved in the service. The effect of this action establishes a system whereby costs of services provided by Veterinary Services at approved quarantine facilities for birds will be collected from the importer and deposited in a trust fund so as to be available to Veterinary Services for defraying expenses involved.

EFFECTIVE DATE: October 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. George P. Pierson, USDA, APHIS, VS, Import-Export Staff, Room 817, Federal Building, 6505 Belcrest Road, Hyattsville, Md. 20782, 301-436-8170.

SUPPLEMENTARY INFORMATION: On August 9, 1978 (43 FR 35458-35459) and August 11, 1978 (43 FR 35682-35683), there was published in the FEDERAL REGISTER an Interim rule which will require importers, effective October 1, 1978, to reimburse Veterinary Services for all costs incurred in providing services required at approved quarantine facilities for the importation of birds, and a schedule of fees to be charged importers for such services.

On August 29, 1978, there was published in the FEDERAL REGISTER (43 FR 38585-38587), a proposed rule which would establish procedures for the collection of such costs from importers and for the deposit of funds so collected in a manner so as to be available to Veterinary Services for defraying expenses involved in this service. A period through September 13, 1978, was provided for receipt of comments on the proposal. A total of 16 comments were received in response to the proposal. Ten of these were from operators of approved quarantine facilities or their representatives, one was from the American Federation of Aviculture, one was from a Regional Poultry and Egg Association, one was from a congressman, and one was from a bird retailer, one was from a State Poulty Federation, one was from a representative of a collective group of 18 membership associations of animal and pet industries.

One comment from a State Poultry Federation endorsed the proposal as an excellent budgetary approach and suggested that collection of fees for service become a permanent feature of the Department's budget.

Three of the 16 comments received stated that the amendments are discriminatory. One of these stated that the proposal favors large importers because only larger importers can afford the deposit required; one comment stated that all costs should be borne by the Federal Government since other Federal agencies do not require recovery of costs for services provided; seven comments stated that the amendments are inflationary; three expressed the opinion that increased cost to the consumer will result; nine objected to the increased cost to importers on the basis that this requirement will force small operators out of business or will otherwise cause hardships for importers; one stated that the procedures proposed will adversely affect the poultry industry, importers, the economy and the general public.

The Department's response to the above comments is as follows: Federal funds which have been used to provide the required services which are associated with the maintenance and operation of approved quarantine facilities for the importation of birds will not be available to the Department as of October 1, 1978. An interim rule was published in the FEDERAL REGISTER on August 9, 1978 (43 FR 35458-35459) and on August 11, 1978 (43 FR 35682-35683) which so advised importers and other interested persons of that fact. The options considered by the Department in lieu of the procedures proposed for the recovery of costs of services provided importers at approved quarantine facilities for the importation of birds were:

1. Removal of the quarantine requirements for birds. This option was not selected in view of the estimated costs ($280 million annually) to the turkey and poultry industries should VVND be established in the United States.

2. Quarantine all imported birds in Government-owned facilities. This option was not selected because of the time and expense which would be required to provide the necessary Government-owned facilities. Further, Government-owned facilities could not be adequately expanded by October 1, 1978, to meet the current needs of bird importers. This would cause a disruption of such importations as of October 1, 1978.

3. Provide Federal services to privately owned approved quarantine facilities without cost to the owner. This option was not selected because the Department will have no appropriated funds with which to provide such service as of October 1, 1978, and the cost to taxpayers would be approximately $2.4 million in 1979 and more in subsequent years. Furthermore, it is inequitable for the general public to pay for services that benefit a small, select group of people. It is equitable for those who receive benefit from such importation to pay the full cost.

4. Prohibition of importation of birds for resale as pets. This option was not selected because this procedure was tried in 1972 and was not successful because of the public demand for a means of importing birds.

Therefore, it was determined that the procedures proposed for the recovery of costs of services provided by Veterinary Services in conjunction with the importation of birds through approved quarantine facilities is the method of choice to resolve the existing problem.

In addition to comments previously summarized, three comments requested that fees required to be deposited be reduced; three others expressed concern because of the possibility of escalating costs; two comments suggested that there will be a decrease in the number of legally imported birds and that those imported will be of poor quality and high price; two comments suggested that certain species may be eliminated from North American markets and that captive breeding programs will be interrupted; seven comments suggested that smuggling activities will increase; and eight comments stated that the placing of proposed procedures into effect will result in endangering the poultry industry.

The Cooperative and Trust Fund Agreement proposed requires that the importer deposit funds with the Deputy Administrator equal to the approximate cost to the Department in furnishing services for two 30-day quarantine periods. The cost of providing services will be continuously reviewed and will be adjusted as indicated on the basis of actual cost studies of services provided to individual importers. No decrease in the number of legally imported birds is anticipated. Some increase in the cost of birds imported will accrue, thus affecting retail prices. Historically, bird smuggling activities were a problem before approved quarantine facilities for birds were established and have continued to be a problem since that date. The overall effect of these amendments on bird smuggling activities is expected to be minimal and will be determined by many factors related to the bird industry. The increased danger of introducing disease into the poultry industry of the United States is proportionate to the illegal entry of poultry and birds and their disease status. Therefore, the degree of increased risk, if any, cannot be determined with accuracy under existing circumstances.

Three comments objected to the examination of records provision in § 92.11(f)(7)(C)(1) of the proposal.

This provision was proposed because the Department's Administrative Regulations appeared to require it for this type of cooperative agreement. However, it has since been determined that this provision is not essential to the Department in the context of this type of cooperative agreement, and that the applicable administrative regulation does not require it in the cooperative agreement herein, and that there are no other laws or regulations requiring that the cooperative agreements herein contain it. Therefore, the examination of records provision in § 92.11(f)(7)(C)(1) of the proposal has been deleted and the subsequent sections therein have been renumbered accordingly.

One comment objected to the nondiscrimination provision contained in § 92.11(f)(7)(C)(2) and to the exclusion provision in § 92.11(f)(7)(C)(3). These provisions are retained in the Cooperative and Trust Fund Agreement as required by the Department's Administrative Regulations.

Other miscellaneous comments were received which were not relevant to the proposal.

Therefore, the proposed regulations are adopted as proposed, except for the deletion of § 92.11(f)(7)(C)(1) of the proposal and consequent renumbering of the subsequent sections therein and certain editorial changes which have been made for the purpose of clarification.

(Section 2 of the Act of February 2, 1903, as amended, section 11 of the Act of May 29, 1884, as amended, and sections 2, 3, 4, and 11 of the Act of July 2, 1962 (21 U.S.C. 111, 114a, 134a, 134b, 134c, and 134f, respectively), and the Act of July 24, 1919, and section 603(a) of the Act of August 30, 1972 (7 U.S.C. 450b and 2201).)

Accordingly, part 92, Title 9, Code of Federal Regulations, is amended in the following respects:

1. In § 92.11(e), the first sentence is amended by deleting the last comma and the phrase ", prior to the issuance of the permit", and a new sentence is added following the amended first sentence to read as set forth below.

2. In § 92.11(f), the introductory paragraph is amended and a new subparagraph (7) is added to read as set forth below.

§ 92.11 Quarantine requirements.

* * * * *

(e) *Birds.* * * * When approved quarantine facilities provided by the importer and approved by the Deputy Administrator are to be used, a Cooperative and Trust Fund Agreement as set forth in § 92.11(f)(7) of the regulations shall be executed by the importer and the Department and appropriate funds deposited with the Deputy Administrator pursuant to the Cooperative and Trust Fund Agreement, prior to the issuance of the permit.

* * * * *

(f) *Standards for approved quarantine facilities and handling procedures for importation of birds.* To qualify for designation as an approved quarantine facility * and retain such approval, the facility and its maintenance and operation must meet the minimum requirements of subparagraphs (1) through (6) of this paragraph (f). The cost of the facility and all costs associated with the maintenance and operation of such facility shall be borne by the importer in accordance with the provisions of subparagraph (7) of this paragraph.

* * * * *

(7) *Cooperative and Trust Fund Agreement for services required by importer at approved quarantine facilities for the importation of birds.* (i) When an approved quarantine facility for the importation of birds is provided by the importer and is approved by the Deputy Administrator as provided in paragraph (e) of this section, a Cooperative and Trust Fund Agreement as set forth in subdivision (iii) of this subparagraph shall be executed by the importer and the Department and, in conjunction therewith, the importer shall deposit with the Deputy Administrator, Veterinary Services, funds adequate to cover all costs incurred by the Department in providing services required for two complete quarantine periods in accordance with the provisions of the Cooperative and Trust Fund Agreement. Amounts collected for services rendered in conjunction with this Cooperative and Trust Fund Agreement shall be deposited so as to be available for defraying the expenses involved in the service.

(ii) The Deputy Administrator is authorized to provide services required by the importer in conjunction with the importations made through approved quarantine facilities for the importation of birds when he determines that the importer has executed a Cooperative and Trust Fund Agreement specified in subdivision (iii) of this subparagraph and has deposited funds in connection therewith as provided in such agreement.

(iii) *Cooperative and Trust Fund Agreement.*

Cooperative and Trust Fund Agreement between————————(name of importer) and U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services

This Agreement is made and entered into by and between————————(name of the importer) hereinafter referred to as the Cooperator, and the U.S. Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services, hereinafter referred to as the Service, with respect to————————(approved quarantine facility and address of facility). Whereas, the Service is authorized pursuant to section 2 of the Act of February 2, 1903, as amended, section 11 of the Act of May 29, 1884, as amended, and section 4 of the Act of July 2, 1962 (21 U.S.C. 111, 114a, and 134c, respectively), to regulate the introduction of animals into the United States in order to prevent the introduction of animal and poultry diseases into the United States; and

Whereas, the Cooperator represents parties interested in the importation of certain birds from countries presently under restrictions for such importation; and

Whereas, the Cooperator is equipped with quarantine facilities approved in accordance with part 92, 9 CFR, for use in importing birds; and

Whereas, the Cooperator has requested the Service to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of birds to insure that they meet the Department's quarantine requirements before release into the United States; and

Whereas, it is the intention of the parties hereto that such cooperation shall be for their mutual benefit and the benefit of the people of the United States;

Now therefore, for and in consideration of the promises and mutual covenants herein contained, the parties hereto do hereby mutually agree with each other as follows:

(A) *The Cooperator agrees:*

(1) To provide quarantine facilities which have been approved according to standards for approved quarantine facilities and handling procedures for importation of birds as provided in part 92 of 9 CFR.

(2) To deposit with the Service upon execution of this agreement the amount of $———— (equal to the approximate cost to the Department for two 30-day quarantine periods) to be used by the Service to defray all expenses incurred by the Service in providing services required, and as funds from that amount are obligated, monthly bills for costs incurred based on official accounting records will be issued to restore the deposit to its original level.

(3) To provide for the maintenance and operation of the approved quarantine facility in accordance with standards for approved quarantine facilities and handling procedures for importation of birds as provided in part 92 of 9 CFR.

(B) *The Service agrees:*

(1) To furnish the services of technical and/or professional personnel needed to conduct inspections, perform laboratory procedures, complete examinations, and supervise the isolation, quarantine, and care and handling of birds being imported to insure that they meet the Department's quarantine requirements before release into the United States.

(2) To provide the Cooperator on a quarterly basis, or within 30 days following receipt of a written request from the Cooperator, with an accounting of funds expended in providing services under paragraph (B)(1) of this agreement. Any unobligated balance

upon termination or expiration of this agreement shall be returned to the Cooperator.

(C) *It is mutually understood and agreed:*

(1) During the performance of this cooperative work, the Cooperator agrees to be bound by the equal opportunity and nondiscrimination provisions as set forth in exhibit B and nonsegregation of facilities provisions as set forth in exhibit C, which are attached hereto and made a part hereof.

(2) No member of or delegate to Congress or resident commissioner, shall be admitted to any share or part of this agreement or to any benefit to arise therefrom; but this provision shall not be construed to extend to this agreement if made with a corporation of its general benefit.

(3) This agreement shall become effective upon date of final signature and shall continue indefinitely. This agreement may be amended by agreement of the parties in writing. It may be terminated by either party upon 30 days written notice to the other party.

Date _____

_____

Cooperator

Date _____

_____

Acting Administrator, Animal and Plant Health Inspection Service, U.S. Department of Agriculture

Since it appears that Department funds will not be available to provide the servies it presently provides approved bird quarantine facilities as of October 1, 1978, if uninterrupted service is to be provided approved bird quarantine facilities as of October 1, 1978, these regulations should be placed into effect immediately. It does not appear that further notice and public participation with respect to these amendments would make additional relevant information available to the Departmeat.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that further notice and other public procedure with respect to the amendments are impracticable and unnecessary and good cause is found for making these amendments effective less than 30 days after publication in the FEDERAL REGISTER.

Done at Washington, D.C., this 28th day of September 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

PIERRE A. CHALOUX, VMD,
Deputy Administrator,
Veterinary Services.

[FR Doc. 78-27825 Filed 9-28-78; 11:43 am]

proposed rules

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.

[3410-05]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

[7 CFR Part 725]

FLUE-CURED TOBACCO

1979 National Marketing Quotas

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture is preparing to announce the national marketing quota for flue-cured tobacco for the 1979-80 marketing year. The quota must be announced by December 1, 1978. This document invites all interested parties to comment and give pertinent information with respect to the determination of the quota and related matters.

DATE: Written comments must be received by November 13, 1978, in order to be sure of consideration.

ADDRESS: Send comments to the Acting Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT:

Robert P. Hieronymus, 202-447-6695.

SUPPLEMENTARY INFORMATION: The Agricultural Adjustment Act of 1938 requires the Secretary to determine and announce the amount of the national marketing quota, the national average yield goal, and the national acreage allotment for the 1979-80 marketing year by December 1, 1978.

The Act defines the "reserve supply level" as 5 percent greater than the "normal supply." The "normal supply" is defined as a normal year's domestic consumption and exports plus 175 percent of a normal year's domestic use and 65 percent of a normal year's exports. A "normal year's domestic consumption" is defined as the average quantity produced and consumed in the United States during the 10 marketing years immediately preceding the marketing year in which the quota must be announced, adjusted for current trends in such consumption. A "normal year's exports" is defined as the average quantity produced in and exported from the United States during the 10 marketing years immediately preceding the marketing year in which the quota must be announced, adjusted for current trends in such consumption.

The reserve supply level for the 1978-79 marketing year was determined to be 2,798 million pounds. This was based on a normal year's domestic consumption of 663 million pounds and a normal year's exports of 510 million pounds (42 FR 61587). The proposed reserve supply level for the 1979-80 marketing year is 2,820 million pounds, based on a normal year's domestic consumption of 658 million pounds and a normal year's exports of 531 million pounds.

The Act (7 U.S.C. 1301(b)) defines "total supply" as the carryover at the beginning of the marketing year (July 1) plus the estimated production in the United States during the calendar year in which the marketing year begins. The total supply for the 1978-79 marketing year is 3,243 million pounds based on carryover of 2,046 million pounds and estimated production of 1,197 million pounds.

The Act (7 U.S.C. 1314c(a)) defines the "National Marketing Quota" for any kind of tobacco for a marketing year as the amount of that kind of tobacco produced in the United States which the Secretary estimates will be used domestically and exported during the marketing year, adjusted upward or downward in an amount as the Secretary, in his discretion, determines is desirable for the purpose of maintaining an adequate supply or for effecting an orderly reduction of supplies to the reserve supply level. The maximum downward adjustment is 15 percent of estimated domestic use and exports.

The amount of flue-cured tobacco produced and utilized domestically during the 1977-78 marketing year was 605 million pounds, and the amount exported was 539 million pounds, farm sales weight basis. The amount of the national marketing quota for the 1978-79 marketing year is 1,117 million pounds, based upon estimated domestic utilization of 645 million pounds and exports of 490 million pounds, with a downward adjustment of 18 million pounds for effecting an orderly reduction of supplies to the reserve supply level (42 FR 61587). For the 1979-80 marketing year utilization in the United States is estimated to be about 605 million pounds and exports are estimated to be about 545 million pounds. The total supply for the 1978-79 marketing year is 423 million pounds more than the proposed reserve supply level, but the amount of the adjustment desirable for maintaining an adequate supply or for effecting an orderly reduction of supplies to the reserve supply level is still being considered.

The Act (7 U.S.C. 1314c(a)) defines the "national average yield goal" for any kind of tobacco as the yield per acre which on a national average basis the Secretary determines will improve or insure the usability of the tobacco and increase the net return per pound to the growers. In making this determination the Secretary shall give consideration to such Federal-State production research data as he deems relevant. The national average yield goal for the 1965-66 and each subsequent marketing year was determined to be 1,854 pounds, and no change is proposed for the 1979-80 marketing year.

The Act (7 U.S.C. 1314c(a)) defines the "national acreage allotment" as the acreage determined by dividing the national marketing quota by the national average yield goal. The national acreage allotment for the 1978-79 marketing year was determined to be 602,481.12 acres (42 FR 61587).

A national acreage factor for apportioning the national acreage allotment to old farms will be determined by dividing the national acreage allotment, less the reserve for new farms and old farms corrections and adjustments by the sum of the 1978 allotments for 1979 old farms prior to adjustments for overmarketings or undermarketings and reductions required for violations. The national acreage factor for the 1978-79 marketing year was 1.0 (42 FR 61587).

A national yield factor will be obtained by dividing the national average yield goal by the national average yield. The national average yield is computed by multiplying the preliminary farm yield for each farm by the acreage allotment determined for the farm prior to adjustments for overmarketings, undermarketings, or reductions required for violations, adding the products, and dividing the sum of the products by the national acreage allotment. The national yield factor for the 1978-79 marketing year was 0.9312 (42 FR 61587).

The Act (7 U.S.C. 1314c(e)) provides that for each marketing year for

which acreage-poundage quotas are in effect a reserve may be established from the national acreage allotment in an amount equivalent to not more than 1 percent of the national acreage allotment to be available for making corrections of errors in farm acreage allotments, adjusting inequities, and for establishing acreage allotments for new farms, which are farms on which no tobacco was produced or considered produced during the immediately preceding 5 years. A reserve of 350 acres was established for the 1978-79 marketing year (42 FR 61587). A similar reserve is proposed for the 1979-80 marketing year.

The Act (7 U.S.C. 1314c(g)) provides that if the Secretary, in his discretion, determined it is desirable to encourage the marketing of grade N2 tobacco, or any grade of tobacco not eligible for price support, in order to meet the normal demands of export and domestic markets, he may authorize the marketing of such tobacco without the payment of penalty or deduction from subsequent quotas to the extent of 5 percent of the marketing quota for the farm on which the tobacco was produced. This has never been authorized under the acreage-poundage program and is not proposed for the 1979-80 marketing year.

PROPOSED RULE

The subject and issues involved in the proposed determinations are:

(1) The amount of the reserve supply level.

(2) The amount of the national marketing quota for the 1979-80 marketing year.

(3) The amount of the national average yield goal.

(4) The amount of acreage to be reserved from the national acreage allotment for making corrections in farm acreage allotments, adjusting inequities, and for establishing acreage allotments for new farms.

(5) Whether the Secretary should implement the provision relating to N2 or other grades of tobacco not eligible for price support.

The amount of the national acreage allotment, the national acreage factor, and the national yield factor are not considered issues in these determinations because they result from mathematical computations based on the determinations outlined in issues (1) through (4) in the preceding paragraph.

The community average yields as computed in 1965 (30 FR 6207, 9875, 14487), will be used for the 1979-80 marketing year. All written submissions will be made available for public inspection from 8:15 a.m. to 4:45 p.m., Monday through Friday, in Room 3741, South Building, 14th and Independence Avenue SW., Washington, D.C.

Executive Order 12044 (43 FR 12661, Mar. 24, 1978), requires at least a 60-day public comment period on any proposed significant regulations except where the Agency determines this is not possible. Because the quota for the 1979-80 flue-cured tobacco marketing year is required by statute to be announced by December 1, 1978, it is hereby found and determined that compliance with the 60-day comment period required by Executive Order 12044 is impossible. Accordingly, comments must be received by November 13, 1978, in order to be assured of consideration.

An approved draft impact analysis statement is available from Thomas A. VonGarlem, Acting Director, Price Support and Loan Division, Room 3741, South Building, P.O. Box 2415, Washington, D.C. 20013.

Signed at Washington, D.C., on September 26, 1978.

RAY FITZGERALD,
Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 78-27494 Filed 9-28-78; 8:45 am]

[3410-05]

[7 CFR Part 729]

1979 PEANUT PROGRAM

Proposed Determinations Regarding National Acreage Allotments and Marketing Quotas

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture proposes with respect to the 1979 crop of peanuts to: a. Determine and proclaim a national poundage quota; b. determine and proclaim a national acreage allotment; and c. apportion such allotment to States. The effect of the determinations is to establish for the 1979 crop of peanuts the national poundage quota and the national acreage allotment and to apportion such allotment to States. This notice invites comments on these proposed determinations.

DATE: Written comments must be received on or before November 13, 1978, to be sure of consideration.

ADDRESS: Send comments to Acting Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, Room 3741, South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT:

Thomas A. vonGarlem (ASCS), 202-447-7954.

SUPPLEMENTARY INFORMATION:

The following determinations are required to be made by the Secretary not later than December 1, 1978, in accordance with provisions of section 358 of the Agricultural Adjustment Act of 1938, as amended, including amendments contained in the Food and Agriculture Act of 1977:

(a) *National poundage quota.* Subsection (1) provides that the Secretary shall, not later than December 1, 1978, announce a national poundage quota for 1979 crop peanuts at not less than 1,596,000 tons. It further provides tht if the Secretary determines that the minimum national poundage quota for any marketing year is insufficient to meet total estimated requirements for domestic edible use and a reasonable carryover, such quota may be increased by the Secretary to the extent determined by the Secretary to be necessary to meet such requirements.

(b) *National acreage allotment.* Subsection (k) provides that the Secretary shall, not later than December 1, 1978, announce a national acreage allotment for 1979 crop peanuts taking into consideration projected domestic use, exports, and a reasonable carryover, subject to the proviso that such allotment shall be not less than 1,614,000 acres.

(c) *Apportionment of national acreage allotment to the States.* Apportionment of the national peanut acreage allotment among the States is governed by paragraph (c)(1) which provides that apportionment among the States shall be on the basis of their shares of the national acreage allotment for the most recent year in which such apportionment was made, except for an amendment providing that the minimum allotment for the State of New Mexico shall not be reduced below the 1977 crop acreage allotment as increased pursuant to a short supply determination under paragraph (c)(2). Under this provision, the 1979 crop of peanuts will be apportioned to the States on the basis of their shares of the 1978 national acreage allotment.

PROPOSED RULE

The Secretary proposes to: (a) Determine and proclaim a national poundage quota, (b) determine and proclaim a national acreage allotment, and (c) apportion such allotment to States.

Before making final determinations, consideration will be given to any relevant data, views, recommendations, or alternative proposals which are submitted in writing to the Acting director of the Price Support and Loan Division, ASCS-USDA.

All written submissions made pursuant to this notice will be made available for inspection from 8:15 a.m. to

4:45 p.m., Monday through Friday, in Room 3741, South Building.

Executive Order 12044 (43 FR 12661, Mar. 24, 1978) requires at least a 60-day public comment period on any proposed significant regulations except where the Agency determines this is not possible or in the best interests of producers. In view of the fact that the national acreage allotment and the national poundage quota for the 1979 crop of peanuts must be announced by December 1, 1978, it is hereby found and determined that compliance with provisions of Executive Order 12044 is impossible. Accordingly, comments must be received on or before November 13 1978, in order to be sure of consideration.

NOTE.—A draft impact analysis is available from Thomas A. VonGarlem (ASCS), 202-447-7954.

NOTE.—The Agricultural Stabilization and Conservation Service, to meet the requirements of the National Environmental Policy Act (Pub. L. 91-190, 42 U.S.C. 4321, et seq.), has developed an environmental assessment on the program and has determined that the proposed action would not constitute a major Federal action significantly affecting the human environment.

Signed at Washington, D.C., on September 26, 1978.

RAY FITZGERALD,
Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 78-27493 Filed 9-28-78; 8:45 am]

[3410-15]

Rural Electrification Administration

[7CFR Part 1701]

ELECTRIC PROGRAM

Revised REA Bulletin 20-2

AGENCY: Rural Electrification Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Rural Electrification Administration (REA) proposes to revise REA Bulletin 20-2, Electric Loan Policies and Application Procedures, to require borrowers to develop energy conservation programs which will aid consumers to use energy in the most efficient manner. The change will amend the list of items required by REA in connection with a loan application by the addition of information related to the borrower's energy conservation program. The added information consists of a copy of the policy approved by the board of directors on energy conservation; a report of the efforts of the borrower to conserve electric energy in the operation of its headquarters and facilities, including the amount this program has reduced annual operating costs and the amount of capital expenditures necessary to achieve the reduction; and a report describing the efforts of the borrower to assist its consumers to make the most efficient use of energy, including a work plan and budget. Borrowers will be required to have an energy conservation program in order to be eligible for REA financing.

DATE: Public comments must be received by REA on or before November 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Harlan M. Severson, Assistant to the Administrator, Rural Electrification Administration, Room 4324, South Building, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-4246.

Notice is hereby given that pursuant to the Rural Electrification Act, as amended (7 U.S.C. 901 et seq.), REA proposes to revise REA Bulletin 20-2. A copy of the proposed revision is being mailed to all REA-financed electric systems. Others may obtain copies of the proposed revision from REA at the address indicated above.

Dated: September 22, 1978.

DAVID A. HAMIL,
Administrator.

[FR Doc. 78-27611 Filed 9-28-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 436 and 446]

[Docket No. 78N-0257]

TETRACYCLINE

Revised Standard Response Line Concentrations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the antibiotic drug regulations by revising the standard response line concentrations for tetracycline antibiotic drugs in order to produce more accurate potency assay results. This revision is made in response to the results of a review conducted by the National Center for Antibiotic Analysis.

DATE: Comments by November 28, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857.

FOR FURTHER INFORMATION CONTACT:

Joan M. Eckert, Bureau of Drugs (HFD-140), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-4290.

SUPPLEMENTARY INFORMATION: The current regulations set forth in § 436.106(a) (21 CFR 436.106(a)) for the microbiological turbidimetric potency assay of the tetracyclines provide for standard response line concentrations that are 64, 80, 100, 125, and 156 percent of the reference concentration of the assay. The tetracyclines referred to in the table appearing in § 436.106(a) are: Chlortetracycline, demeclocycline, doxycycline, methacycline, minocycline, oxytetracycline, rolitetracycline, and tetracycline. The reference concentration of the assay is the midpoint concentration of the standard response line. A review of the standard response lines by FDA's laboratory, the National Center for Antibiotic Analysis, shows that variations in the assay prevent the straight line portion of the curve from extending far enough to include either the low- or high-standard response line concentrations of 64 and 156 percent. This problem can be eliminated by (a) raising the low concentration from 64 percent to 80 percent, (b) lowering the high concentration from 156 percent to 125 percent, and (c) recalculating the second and fourth standard response line concentrations. The Food and Drug Administration has determined that when the samples are diluted to concentrations within the 80- to 125-percent range, more accurate potency concentration estimates are obtained.

This proposal changes the midpoint concentration of the dose response line for minocycline from 0.100 microgram per milliliter to 0.085 microgram per milliliter. This change is necessary because FDA has found that the midpoint concentration of 0.100 microgram per milliliter results in curvature at high concentrations causing crescent-shaped dose response lines outside the limits of linearity. The proposed midpoint concentration of 0.085 microgram per milliliter produces dose response lines that are usually statistically linear. The other concentrations on the minocycline dose response lines are revised accordingly.

The Commissioner has determined that this document does not contain an agency action covered by § 25.1(b) (21 CFR 25.1(b)); therefore, consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59

Stat. 463 as amended (21 U.S.C. 357)) and under authority delegated to the Commissioner (21 CFR 5.1), Parts 436 and 446 are amended as follows:

1. Part 436 is amended in § 436.106(a) by revising the last column of the table. As revised, the table reads as follows:

§ 436.106 Microbiological turbidimetric assay.

* * * * *

(a) * * *

Antibiotic	Working standard stock solutions: Drying conditions (method number as listed in sec. 436.200)	Working standard stock solutions: Initial solvent	Working standard stock solutions: Diluent (solution number as listed in § 436.101(a))	Working standard stock solutions: Final concentration	Working standard stock solutions: Storage time under refrigeration	Standard response line concentrations: Diluent (solution number as listed in sec. 436.101(a))	Standard response line concentrations: Final concentrations—units or micrograms of antibiotic activity per milliliter
Amikacin	Not dried		Distilled water	1 mg	2 weeks	Distilled water.	8.0, 8.9, 10.0, 11.2, 12.5 μg.
Candicidin[1]	6		Dimethyl sulfoxide	1 mg	Use same day	do	0.030, 0.043, 0.060, 0.085, 0.120 μg. (Prepare standard response line simultaneously with the sample solution.)
Capreomycin	5	Distilled water.		1 mg	7 days	do	64, 80, 100, 125, 156 μg.
Chloramphenicol	Not dried	Ethyl alcohol (10,000 μg. per ml.).		1 mg	1 mo	1	2.00, 2.24, 2.50, 2.80, 3.12 μg.
Chlortetracycline	do		0.01*N* HCl	1 mg	4 days	4	0.048, 0.054, 0.060, 0.067, 0.075 μg.
Cycloserine	1		Distilled water	1 mg	1 mo	Distilled water.	32.0, 40.0, 50.0, 62.5, 78.1 μg.
Demeclocycline	1		0.1*N* HCl	1 mg	4 days	4	0.080, 0.089, 0.100, 0.112, 0.125 μg.
Dihydrostreptomycin	5		Distilled water	1 mg	30 days	Distilled water.	24.0, 26.8, 30.0, 33.5, 37.5 μg.
Doxycycline	Not dried		0.1*N* HCl	1 mg	5 days	4	0.080, 0.089, 0.100, 0.112, 0.125 μg.
Gramicidin	1		95 pct ethyl alcohol	1 mg	30 days	95 pct ethyl alcohol.	0.028, 0.034, 0.040, 0.048, 0.057 μg.
Kanamycin	Not dried		Distilled water	1 mg	1 mo	Distilled water.	8.0, 8.9, 10.0, 11.2, 12.5 μg.
Methacycline	1		13	1 mg	7 days	4	0.048, 0.054, 0.060, 0.067, 0.075 μg.
Minocycline	Not dried		0.1*N* HCl	1 mg	2 days	4	0.068, 0.076, 0.085, 0.095, 0.106 μg.
Oxytetracycline	do		0.1*N* HCl	1 mg	4 days	4	0.192, 0.215, 0.240, 0.268, 0.300 μg.
Rolitetracycline	1		Methanol	1 mg	1 day	4	0.192, 0.215, 0.240, 0.268, 0.300 μg.
Spectinomycin	Not dried		Distilled water	1 mg	1 mo	Distilled water.	24.0, 26.8, 30.0, 33.5, 37.5 μg.
Streptomycin	1		do	1 mg	30 days	do	24.0, 26.8, 30.0, 33.5, 37.5 μg.
Tetracycline	Not dried		0.1*N* HCl	1 mg	1 day	4	0.192, 0.215, 0.240, 0.268, 0.300 μg.
Tobramycin	do		Distilled water	1 mg	2 weeks	Distilled water.	2.00, 2.236, 2.5, 2.795, 3.125 μg.
Troleandomycin	1		15	1 mg	Use same day	1	16.0, 20.0, 25.0, 31.2, 39.0 μg.
Tyrothricin[2]							
Viomycin	1		Distilled water	1 mg	7 days	Distilled water.	64, 80, 100, 125, 156 μg.

[1] Use sterile equipment for all stages of this assay.
[2] The gramicidin working standard and the gramicidin standard response line concentrations are used for the assay of tyrothricin.

* * * * *

2. Part 446 is amended:

§ 446.60 [Amended]

a. In § 446.60 *Minocycline hydrochloride*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160a [Amended]

b. In § 446.160a *Minocycline hydrochloride tablets*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160b [Amended]

c. In § 446.160b *Minocycline hydrochloride capsules*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.160c [Amended]

d. In § 446.160c *Minocycline hydrochloride oral suspension*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

§ 446.260 [Amended]

e. In § 446.260 *Sterile minocycline hydrochloride*, by revising the figure "0.100" in the last sentence of paragraph (b)(1) to read "0.085".

Interested persons may, on or before November 28, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with

the Hearing Clerk, Food and Drug Administration.

Dated: September 20, 1978.

MARY A. MCENIRY,
Assistant Director for Regulatory Affairs, Bureau of Drugs.

[FR Doc. 78-26951 Filed 9-28-78; 8:45 am]

[4210-01]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Federal Insurance Administration

[24 CFR Part 1917]

[Docket No. FI-2835]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for City of Charlottesville, Independent City, Va.; Correction

AGENCY: Federal Insurance Administration, HUD.

ACTION: Correction of proposed rule.

SUMMARY: This document corrects a proposed rule on base (100-year) flood elevations for the city of Charlottesville, Va., that appeared on page 18238 of the FEDERAL REGISTER, of April 5, 1977 (42 FR).

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

The following corrections are made:

Along Moores Creek at Meridian Street (extended) with an elevation of 353 feet.

(National Flood Insurance Act of 1968 (title XIII of Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: September 13, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-27453 Filed 9-28-78; 8:45 am]

[4210-01]

[24 CFR Part 1917]

[Docket No. FI-4431]

NATIONAL FLOOD INSURANCE PROGRAM

Proposed Flood Elevation Determinations for the Borough of Shoemakersville, Berks County, Pa., Correction

AGENCY: Federal Insurance Administration, HUD.

ACTION: Correction of proposed rule.

SUMMARY: The proposed flood elevation determinations for the borough of Shomakersville, Berks County, Pa. (43 FR 38865, Aug. 31, 1978), was erroneously listed as the borough of Shoemakersville, Bucks County, Pa. This notice will serve as a correction of that publication.

FOR FURTHER INFORMATION CONTACT:

Mr. Richard Krimm, Assistant Administrator, Office of Flood Insurance, Room 5270, 451 Seventh Street SW., Washington, D.C. 20410, 202-755-5581 or toll-free line 800-424-8872.

(National Flood Insurance Act of 1968 (title XIII of Housing and Urban Development Act of 1968), effective Jan. 28, 1969 (33 FR 17804, Nov. 28, 1968), as amended (42 U.S.C. 4001-4128); and Secretary's delegation of authority to Federal Insurance Administrator, 43 FR 7719.)

Issued: September 13, 1978.

GLORIA M. JIMENEZ,
Federal Insurance Administrator.

[FR Doc. 78-27454 Filed 9-28-78; 8:45 am]

[6560-01]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

[FRL 976-3; Docket No. 664A]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Delayed Compliance Order for Housatonic Ever-Float Co., Shelton, Conn.

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The Purpose of this notice is to withdraw a prior FEDERAL REGISTER notice proposing a Delayed Compliance Order for The Housatonic Ever-Float Co. at Shelton, Conn. This action is being taken because The Housatonic Ever-Float Co. is no longer in violation of the Connecticut State Implementation Plan provisions covered by the proposed Order.

DATE: This withdrawal is immediately effective.

FOR FURTHER INFORMATION CONTACT:

Mr. Sam Silverman, Attorney, Enforcement Branch, Enforcement Division, U.S. Environmental Protection Agency, Region I Office, JFK Federal Building, Boston, Mass. 02203, 617-223-5600.

SUPPLEMENTARY INFORMATION: A FEDERAL REGISTER notice published at 43 FR 29805, July 11, 1978, solicited public comments and offered the opportunity to request a public hearing on a proposed Delayed Compliance Order to be issued by The Connecticut Department of Environmental Protection to the Housatonic Ever-Float Co. at Shelton, Conn. The Housatonic Ever-Float Co. has subsequently achieved compliance with the Connecticut State Implementation Plan regulations covered by the Order. Compliance was achieved by reformulating compounds to meet Connecticut organic compound emission limitations.

In consideration of the foregoing, the proposal published in the FEDERAL REGISTER, 43 FR 29805 on July 11, 1978, entitled "Proposed Delayed Compliance Order for The Housatonic Ever-Float Co., Shelton, Conn.," is hereby withdrawn.

Dated: September 18, 1978.

WILLIAM R. ADAMS, Jr.,
Regional Administrator, Region I.

[FR Doc. 78-27411 Filed 9-28-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 976-4; Docket No. 603B]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Delayed Compliance Order for The Turner & Seymour Manufacturing Co., Torrington, Conn.

AGENCY: Environmental Protection Agency.

ACTION: Withdrawal of notice of proposed rulemaking.

SUMMARY: The purpose of this notice is to withdraw a prior FEDERAL REGISTER notice proposing a Delayed Compliance Order for The Turner & Seymour Manufacturing Co. at Torrington, Conn. This action is being taken because The Turner & Seymour Manufacturing Co. is no longer in violation of the Connecticut State Implementation Plan provisions covered by the proposed Order.

DATE: This withdrawal is immediately effective.

FOR FURTHER INFORMATION CONTACT:

Mr. Sam Silverman, Attorney, Enforcement Branch, Enforcement Division, U.S. Environmental Protection Agency, Region I Office, JFK Federal Building, Boston, Mass. 02203, 617-223-5600.

SUPPLEMENTARY INFORMATION: A FEDERAL REGISTER notice published at 43 FR 20023, May 10, 1978, solicited public comments and offered the opportunity to request a public hearing on a proposed Delayed Compliance Order to be issued by The Connecticut Department of Environmental Protection to The Turner & Seymour Manufacturing Co. at Torrington, Conn. The Turner & Seymour Manufacturing Co. has subsequently achieved compliance with the Connecticut State Implementation Plan regulations covered by the Order. Compliance was achieved by installation of a fabric filter emission control system.

In consideration of the foregoing, the proposal published in the FEDERAL REGISTER, 43 FR 20023 on May 10, 1978, entitled "Proposed Delayed Compliance Order for The Turner & Seymour Manufacturing Co., Torrington, Conn." is hereby withdrawn.

Dated: September 18, 1978.

WILLIAM R. ADAMS, Jr.,
Regional Administrator,
Region I.

[FR Doc. 78-27410 Filed 9-28-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 978-2; Docket No. VII-78-DCO-11]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued by Iowa Department of Environmental Quality to Interstate Power Co., Kapp Station, Clinton, Iowa

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the Iowa Department of Environmental Quality to Interstate Power Co., Kapp Station. The order requires the company to bring air emissions from its unit No. 2 in Clinton into compliance with certain regulations contained in the federally approved Iowa State implementation plan (SIP) by September 29, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before October 30, 1978.

ADDRESSES: Comments should be submitted to Director, Enforcement Division, EPA, Region VII, 1735 Baltimore, Kansas City, Mo. 64108. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Peter J. Culver or Henry F. Rompage, EPA, Region VII, 1735 Baltimore, Kansas City, Mo. 64108, 816-374-2576.

SUPPLEMENTARY INFORMATION: Interstate Power Co. operates an electric powerplant at Clinton, Iowa. The order under consideration addresses emissions from Kapp Station unit No. 2 at the facility, which are subject to subrule 400—4.3(2)b Iowa Administrative Code, Combustion for indirect heating. The regulation limits the emissions of particulates, and is part of the federally approved Iowa State implementation plan. The order requires final compliance with the regulation by September 29, 1979, through installation of an electrostatic precipitator. The source has consented to the terms of the order. The source has completed increments A.1 to 5 and B.1 to 4 contained in the order.

Because this order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. The elements of the appropriate paragraphs of subsection 113(d) have been met.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the Act against the source for violations of the regulation covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (section 304) would be similarly precluded. If approved, the order would also constitute an addition to the Iowa SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

The provisions of 40 CFR Part 65 will be promulgated by EPA soon,[1] and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the Act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (Apr. 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601.)

Dated: September 20, 1978.

KATHLEEN Q. CAMIN,
Regional Administrator,
Region VII.

BEFORE THE IOWA DEPARTMENT OF ENVIRONMENTAL QUALITY, AIR QUALITY COMMISSION, DES MOINES, IOWA

ORDER

Docket No. 77-A-050

In the Matter of Interstate Power Co., M. L. Kapp Station, Clinton, Iowa

Whereas, employees of the Department of Environmental Quality reviewed a stack emission test on unit No. 2 at Interstate Power Co.'s Kapp Station in Clinton, Iowa, and determined that the emissions from unit No. 2 exceeded the emission standards of subrule 400—4.3(2)b I.A.C.

Whereas the said subrule is a part of the federally approved implementation plan applicable to air quality control region 069 in which the Interstate Power Co. in Clinton, Iowa, is located:

Whereas Interstate Power Co. has agreed to waive its rights to a contested case hearing under the Iowa Administrative Procedure Act and to waive its rights under section 455B.17 of the Iowa code with respect to an alleged violation;

Whereas Interstate Power Co. is hereby given notice that in the event it fails to meet any requirment of this order, it will be subject to civil penalties for such noncompliance, and that if it fails to achieve final compliance as specified in subparagraph B-7 by July 1, 1979, it shall be required to pay a noncompliance penalty under section 120 of the Clean Air Act as amended (42 U.S.C. 7420) or under Iowa law subsequently enacted to obtain delegation under that section;

Whereas, after full consideration of relevant facts, including the seriousness of the violation and any good faith efforts to comply, compliance with the order below is reasonable and expeditious; and

Whereas, the company acknowledges that it is prepared to proceed as scheduled in the order to achieve the required compliance in consideration for the Air Quality Commission's agreement that for such period of time as the company is in compliance with

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[1] Published in the FEDERAL REGISTER of Sept. 28, 1978.

said schedule, this order shall stand in lieu of those administrative, legal, and equitable remedies available to the Air Quality Commission or related Iowa agencies regarding the alleged violation with respect to subrule 400-4.3(2)b.

Therefore, it is ordered, By the Air Quality Commission:

A. That Interstate Power Co. complete the following acts with respect to the unit No. 2 at its plant in Clinton, Iowa, on or before the dates specified.

1. June 1, 1977—Select flue gas conditioning supplier.

2. July 15, 1977—Receive equipment at site.

3. August 1, 1977—Complete installation of equipment.

4. March 6, 1978—Conduct particulate emission tests.

5. March 27, 1978—Submit test results and achieve final compliance with subrule 400—4.3(2)b I.A.C.

B. That Interstate Power Co. complete the following on or before the dates specified. If the flue gas conditioning program is not successful, additional electorstatic precipitator surface will be installed on unit No. 2.

1. December 15, 1977—Submit final control plan.

2. March 15, 1977—Select precipitator manufacturer.

3. May 1, 1978—Apply for permit from DEQ.

4. August 15, 1978—Start construction.

5. May 18, 1979—Complete construction.

6. May 29, 1979—Conduct particulate emission tests.

7. June 29, 1979—Submit test results to DEQ, and achieve final compliance with subrule 400—4.3(2)b I.A.C.

C. That until final compliance as specified in subparagraph B-7 is achieved, Interstate Power Co. shall comply with the following interim requirements:

In the event that part B is necessary, gas conditioning will be continued, if effective in reducing emissions, until final compliance has been demonstrated as a result of implementing the program under part B.

D. That Interstate Power Co. shall monitor such emissions and report such information as required by the Executive Director of the Department of the Environmental Quality pursuant to chapter 400—2(455B) I.A.C.

E. That Interstate Power Co., prior to the initiation of onsite construction or installation of emission control equipment required by paragraph B-4, obtain a permit for the proposed equipment or related control equipment from the Permits Section of the Air and Land Quality Division of the Department of Environmental Quality, as defined in subrule 400—3.1 I.A.C.

F. That Interstate Power Co. certify to the Chief of the Surveillance Section of the Air and Land Quality Division of the Department of Environmental Quality no later than seven (7) days after the deadline for completing such increment of progress, whether such increment has been achieved; if an increment has not been achieved by the deadline date, a full report of the reasons why the increment was not achieved and of whether the failure is expected to put the subsequent deadline dates in jeopardy should be submitted.

G. That Interstate Power Co., 15 days prior to conducting the performance tests required by paragraphs A-4 and B-6, give notice of such scheduled test to the Chief of Surveillance Section to afford him an opportunity to have an observer present.

H. That in the event the Air Quality Commission proposes to modify this order for any reason, the signature of the company hereon and the waiver of the company herein would not be binding on the company.

I. That this order shall be binding upon the company, its successors and assigns, and upon the Air Quality Commission, its successors and assigns.

Dated: January 19, 1978.

HERBERT L. CAMPBELL,
Chairman, Air Quality Commission.

Dated: December 20, 1977.

D. J. CARLSON,
Vice President, Interstate Power Co.

[FR Doc. 78-27405 Filed 9-28-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 978-1]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Approval of an Administrative Order Issued by the State of Idaho Department of Health and Welfare to U&I Sugar, Inc.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the State of Idaho Department of Health and Welfare to U&I Sugar, Inc. The order requires the company to bring air emissions from its sugar refinery in Idaho Falls, Idaho, into compliance with certain regulations contained in the federally-approved Idaho State Implementation Plan (SIP), by July 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before October 30, 1978.

ADDRESS: Comments should be submitted to Director, Enforcement Division, EPA, Region 10, 1200 Sixth Avenue, Seattle, Wash. 98101. The State order, supporting material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

John Pfander, EPA, Idaho Operations Office, 422 West Washington, Boise, Idaho 83702, 208-384-1450.

SUPPLEMENTARY INFORMATION: U&I, Inc. operates a sugar refinery at Idaho Falls, Idaho. The order under consideration addresses emissions from the Erie No. 2 boiler at the facility, which is subject to regulations E, G, H, and I of the rules and regulations for the Control of Air Pollution in Idaho. The regulations limit the emissions of particulate matter and visible emissions, and is part of the federally-approved Idaho State Implementation Plan. The order requires final compliance with the regulation by July 1, 1979. The source has consented to the terms of the order and will satisfy the particular increments contained in the order. EPA is proposing to approve only those portions of the operating permit covered by 113(d) of the Clean Air Act which are necessary to make up a valid delayed compliance order.

Because this order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA proposes to approve the order because it satisfies the appropriate requirements of this subsection.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the Act against the sources for violations of the regulation covered by the order during the period the order is in effect.

Enforcement against the source under the citizen suit provision of the Act (sec. 304) would be similarly precluded. If approved, the order would also constitute an addition to the Idaho SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65.

(42 U.S.C. 7413, 7601)

Dated: September 20, 1978.

DONALD P. DUBOIS,
Regional Administrator,
Region 10.

[FR Doc. 78-27406 Filed 9-28-78; 8:45 am]

[6560-01]

[40 CFR Part 65]

[FRL 976-6]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Notice of Proposed Approval of an Administrative Order Issued by Virginia State Air Pollution Control Board to U.S. General Services Administration

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to approve an administrative order issued by the Virginia State Air Pollution Control Board to the U.S. General Services Administration (GSA). The order requires GSA to bring air emissions from its Virginia heating and refrigeration plant in Arlington, Va. into compliance with certain regulations contained in the federally-approved Virginia State Implementation Plan (SIP) by June 1, 1979. Because the order has been issued to a major source and permits a delay in compliance with provisions of the SIP, it must be approved by EPA before it becomes effective as a delayed compliance order under the Clean Air Act (the Act). If approved by EPA, the order will constitute an addition to the SIP. In addition, a source in compliance with an approved order may not be sued under the Federal enforcement or citizen suit provisions of the Act for violations of the SIP regulations covered by the order. The purpose of this notice is to invite public comment on EPA's proposed approval of the order as a delayed compliance order.

DATE: Written comments must be received on or before October 30, 1978.

ADDRESS: Comments should be submitted to Director, Enforcement Division, EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pa. 19106. The State order, supporting, material, and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT:

Mr. Gary Gross, Air Enforcement Branch, 3EN12, EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pa. 19106, telephone 215-597-8907.

SUPPLEMENTARY INFORMATION: GSA operates a heating plant at the Pentagon Office Building in Arlington, Va. The order under consideration addresses emissions from coal-fired boiler Nos. 2, 3, 4, and 5 at the facility, which are subject to section 4.02.01 and 4.03.01 of the Commonwealth of Virginia regulations for the control and abatement of air pollution. The regulations limit the emissions of visible emissions and particulate matter, and are part of the federally approved Virginia State Implementation Plan. The order requires final compliance with the regulations by June 1, 1979, through installation of electrostatic precipitators. The schedule for compliance contained in the order was developed by GSA in cooperation with the State air pollution control board. Because this order has been issued to a major source of particulate emissions and permits a delay in compliance with the applicable regulation, it must be approved by EPA before it becomes effective as a delayed compliance order under section 113(d) of the Clean Air Act (the Act). EPA may approve the order only if it satisfies the appropriate requirements of this subsection. Based on the information presently available, the Agency believes the statutory requirements are met by this order. Section 18 of the State order states, "the Board may modify this order for good cause shown by GSA, or on its own motion after notice to GSA and an opportunity for hearing." In accordance with section 113(d)(2) of the Act, no such modification shall take effect until such time as the Administrator determines that such modification satisfies the requirements of the Act.

If the order is approved by EPA, source compliance with its terms would preclude Federal enforcement action under section 113 of the Act against the source for violations of the regulations covered by the order during the period the order is in effect. Enforcement against the source under the citizen suit provision of the Act (sec. 304) would be similarly precluded. If approved, the order would also constitute an addition to the Virginia SIP.

All interested persons are invited to submit written comments on the proposed order. Written comments received by the date specified above will be considered in determining whether EPA may approve the order. After the public comment period, the Administrator of EPA will publish in the FEDERAL REGISTER the Agency's final action on the order in 40 CFR Part 65. The provisions of 40 CFR Part 65 will be promulgated by EPA soon, and will contain the procedure for EPA's issuance, approval, and disapproval of orders under section 113(d) of the Act. In addition, part 65 will contain sections summarizing orders issued, approved, and disapproved by EPA. A prior notice proposing regulations for part 65, published at 40 FR 14876 (April 2, 1975), will be withdrawn, and replaced by a notice promulgating these new regulations.

(42 U.S.C. 7413, 7601)

Dated: August 21, 1978.

JACK J. SCHRAMM,
Acting Regional
Administrator, Region III.

[FR Doc. 78-27408 Filed 9-28-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[49 CFR Ch. X]

[Ex Parte No. 344]

TERMINAL PERFORMANCE STANDARDS GOVERNING THE TRANSPORTATION OF NONPERISHABLE COMMODITIES

Participation Notice and Procedural Time Schedule

AGENCY: Interstate Commerce Commission

ACTION: Notice to persons interested in participating in this proceeding and procedural time schedule for filing and cross-service of pleadings.

SUMMARY: This document extends the time for filing comments; provides for the development and service of a participation list; orders all parties to cross-service their pleadings and makes provision for the filing of replies in the proceeding relating to terminal performance standards governing the transportation of nonperishable commodities published at 43 FR 33774, August 1, 1978.

DATES: Any person intending to participate actively in this proceeding shall notify the Commission by filing an original and one copy of a statement of intent to participate. Statements must be filed with the Commission on or before October 9, 1978.

Persons who have submitted comments prior to the publication of this notice are to be regarded as participants in this proceeding and do not have to file a statement of intent to participate.

The Office of Proceedings shall then send to all participants a list of names and addresses of all parties. Thereafter, all parties must serve copies of their initial comments and all subsequent pleadings upon all other parties.

The filing and service of pleadings shall be as follows: initial comments by respondents and all other partici-

pants are due by October 16, 1978; and 20 days thereafter, replies by respondents and all other participants.

ADDRESSES: Participation statements and pleadings should be sent to: Office of Proceedings, Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

Janice M. Rosenak, or Harvey Gobetz, phone: 202-275-7693.

By notice of proposed rulemaking, 345 I.C.C. 2971, published in the FEDERAL REGISTER on August 1, 1978 (43 FR 33774), the Commission instituted this proceeding to establish performance standards governing terminal operations in the transportation of nonperishable commodities. Proposed regulations were set forth in the notice. The Commission indicated that this was not an adversary proceeding. Therefore, to expedite procedures and to avoid delay and expense, the Commission ordered only the filing of comments by respondents and interested parties 30 days from the date of publication of the notice of proposed rulemaking in the FEDERAL REGISTER. The Commission further ordered that one set of these comments be made available in the Secretary's Office for public inspection during regular business hours of the Commission. By decision served August 24, 1978, and by FEDERAL REGISTER notice published on August 30, 1978 (43 FR 38736), an extension of time for the filing of comments, requested by certain railroad respondents, was granted to all parties to October 16, 1978.

On September 6, 1978, the Commission received a letter from the North Dakota Public Service Commission (NDPSC). This letter was made part of the initial comment filed in this proceeding by NDPSC on August 28, 1978. NDPSC requested the Commission to develop and serve a participation list in this proceeding; order all parties to cross-service their pleadings; and make provision for the filing of the replies to the initial comments.

In view of the importance of this proceeding, the extension of time granted for the filing of comments, and the fact that many parties do not have the ability to visit the Secretary's Office and review the comments, the requests made by NDPSC are granted.

Persons interested in participating in this proceeding shall comply with the instructions and time schedule as set forth under "Dates".

Issued in Washington, D.C., September 13, 1978.

By the Commission, Chairman O'Neal.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-27065 Filed 9-28-78; 8:45 am]

[3510-22]
[4310-55]

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[50 CFR Part 403]

FISH AND WILDLIFE COORDINATION ACT

Notice of Intent to Proposed Rules

AGENCY: National Oceanic and Atmospheric Administration, Commerce; Office of the Secretary, Interior.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: In his water policy memorandum dated July 12, 1978, President Carter directed the Departments of Commerce and the Interior to publish regulations to implement the Fish and Wildlife Coordination Act. The Act concerns the conservation of wildlife in projects involving the control or modification of any stream or other body of water. Public, Congressional, State, and Federal comment is requested to assist those agencies in preparing proposed rules to implement the Act. (FWCA, Pub. L. 85-624, 72 Stat. 563, 16 U.S.C. 661 et seq. (1976).)

DATE: Comments must be received by October 31, 1978. Responses will not be provided.

ADDRESS: Send written comments to William W. Garner, Office of the Solicitor, U.S. Department of the Interior, Room 6544, Washington, D.C. 20240, 202-343-2172.

FOR FURTHER INFORMATION CONTACT:

Karl F. Stutzman, Fish and Wildlife Service, U.S. Department of the Interior, Room 3251, Washington, D.C. 20240, 202-343-5715.

William W. Garner, Office of the Solicitor, U.S. Department of the Interior, Room 6544, Washington, D.C. 20240, 202-343-2172.

James R. Chambers, National Marine Fisheries Service, 3300 Whitehaven Street NW., Page Building II, Room 188, Washington, D.C. 20235, 202-634-7490.

Eric Erdheim, Office of General Counsel, National Oceanic and Atmospheric Administration, 3300 Whitehaven Street NW., Page Building II, Room 400, Washington, D.C. 20235, 202-634-4224.

SUPPLEMENTARY INFORMATION: In a water policy memorandum dated July 12, 1978, President Carter directed that—

> The Secretary of the Interior in cooperation with the Secretary of Commerce shall promulgate regulations by March 1, 1979, defining the requirements and procedures that mut be met for fully complying with the Fish and Wildlife Coordination Act. * * * Then, not later than 3 months after promulgation of such final regulations, Federal agencies with consultative responsibilities under the * * * [FWCA] shall publish * * * separate procedures to be followed in implementing the regulations * * *. These procedures shall be reviewed, and if consistent with the regulations, approved within 60 days by the Secretary of the Interior.

The regulations referred to by the President (hereafter "rules") would be published jointly by the Secretaries of the Interior and Commerce using the rulemaking procedures for "significant rules" which are contemplated by Executive Order (E.O.) 12044.

These rules will be joint rules because of the division of FWCA jurisdiction between the Departments of Commerce and the Interior made by Reorganization Plan No. 4 of 1970 (published in the appendix to Title 5, United States Code).

THE FWCA

The FWCA requires Federal agencies (hereinafter "action agencies") which propose, or are authorized, to undertake the impoundment, diversion, deepening, or other control or modification of waters of any stream or other body of water, or which are asked to issue permits or licenses for such activity, to accord wildlife conservation equal consideration with other features of such projects throughout their planning and decisionmaking processes. It requires such agencies, or applicants to such agencies, to first consult with State and Federal wildlife agencies with a view to ascertaining what project facilities, operations, or measures may be considered necessary by those agencies to mitigate and compensate for project-occasioned losses to wildlife resources, as well as to enhance those resources.

The FWCA further requires that the reports and recommendations on the wildlife aspects of such projects which are received by action agencies shall be presented to action agency decisionmakers and (where applicable) the Congress, and that the action agencies shall give full consideration to those reports. Action agencies are required to include in project plans such means and measures for wildlife conservation as they may find justifiable to obtain maximum overall project benefits, and the costs thereof are to be considered integral to those of the project.

Subject to certain project exceptions, the FWCA itself authorizes Fed-

eral agencies which have been authorized to construct or operate water control projects, to modify or add to project structures or operations, and to acquire lands, waters, or interest therein, in order to promote the conservation of wildlife resources associated with such projects.

NEED FOR FWCA REGULATIONS

Most action agencies have not adopted procedures implementing the FWCA. Where they have, there are disparities in interpretation and program emphasis, and there is often little opportunity for the public to participate in decisions by final action agency decisionmakers as to which wildlife conservation measures will be adopted. The FWCA vests that ultimate decisionmaking authority in the action agency, or, in the case of most Federal projects, the Congress.

Despite an increasing number of legal cases raising FWCA issues, this piecemeal approach is not as effective as regulations and has not provided the comprehensive level of FWCA compliance called for by the President. These rules should also advance the President's directive that Federal agencies should coordinate and simplify environmental review requirements.

MAJOR SUBJECT MATTER TO BE INCLUDED IN FWCA RULES

It is not the purpose of this notice to describe the proposed content of the rules in any detail. However, it is anticipated that these rules will include—

(a) Interpretive rules resolving differing constructions of the FWCA and procedures for consultation on wildlife conservcation needs among State and Federal wildlife agencies, project agencies, and the Congress,

(b) Procedures for public and State participation in the FWCA planning process,

(c) Procedures for resolution of future interagency differences on interpretation of the FWCA, and of differences on what wildlife conservation measures should be included in project plans,

(d) Guidelines for determining when the discretionary decisions of project agencies to incorporate wildlife mitigation or enhancement measures at previously authorized projects should be referred to the Congress, and

(e) As directed by the President, methods for determining adequate measures to mitigate losses to fish and wildlife.

VIEWS REQUESTED

1. *Are the economic consequences of these rules likely to be such as to require preparation of a "regulatory analysis," within the meaning of E.O. 12044?* Because of the relationship of these rules to the programs of other agencies, a determination has been made that these joint rules will be "significant," within the meaning of E.O. 12044. However, a determination whether a "regulatory analysis" need be prepared has been withheld pending receipt of comments.

The President's criteria would require regulatory analyses for all rules which will result in (a) an annual effect on the economy of $100 million or more, or (b) a major increase in costs or prices for individual industries, levels of Government, or geographic regions. E.O. 12044, sec. 3(a)(1). Additional criteria have been proposed by the Department of the Interior at 43 FR 22573 (May 25, 1978), and by the National Oceanic and Atomspheric Administration at 43 FR 23188 (May 30, 1978).

The FWCA places responsibilities with budgetary consequences upon State and Federal wildlife agencies, Federal action agencies, and Office of Management and Budget (OMB) (review of budget requests). If, as a result of these FWCA regulations, action agencies incorporate wildlife conservation measures at *Federal* projects which require the expenditure of money and manpower, nonpublic parties who purchase vendible services of such projects (through which the costs of such measures are reimbursed to the U.S. Treasury) would be economically effected.

Similarly, private applicants for water-related project permits and licenses to which the FWCA rules would apply might be required to expend additional moneys to incorporate wildlife conservation measures into their project plans.

Your views are sought as to the magnitude of the foregoing categories of expenditures at present, computed on an annual basis. Concrete documentation is requested.

2. *Is there a need for guidelines for congressional review of proposals to add wildlife conservation measures to projects?* In 1962 the Solicitor of the Department of the Interior issued an opinion that section 2(c) of the FWCA constitutes a standing authority for appropriations to add wildlife conservation measures to most authorized Federal projects, and that section 3(c) of the FWCA does not require specific congressional authorization of land acquisition (in particular) which may be a part of such a proposal. 69 I.D. 224 (1962). The Solicitor found that the Congress intended to exercise control over the land acquisition aspects of such proposals through the appropriations process. There is no dispute that, subject to appropriations where required, proposals not involving land acquisition are authorized upon adoption by the construction agency head.

The underlying policy question presented is: Should not the Congress nevertheless be involved in review of such proposals? Should referrals be made to the Congress where no further appropriation is required to carry out some or all aspects of such proposals? Should the size of the necessary expenditure be a determinant of whether some or all categories of wildlife conservation measures are referred to the Congress? The Department of the Interior generally tends to favor specific congressional authorization of changes in its authorized water projects.[1] Are all these proposals really substantial enough to warrant special congressional attention?

3. *Should applicants for all, or certain categories of, Federal permits or licenses be required to first consult with wildlife agencies before submitting applications to action agencies? If so, how should these categories be defined?* One assumption advanced in favor of such a requirement is that the potential for confrontation between wildlife agencies, on the one hand, and action agencies or applicants on the other, can be avoided, if there is wildlife agency input at a flexible stage of the potential applicant's planning process. Wildlife agencies could assist action agencies and applicants in developing plans which may be less environmentally damaging, and therefore more acceptable to reviewing agencies and the public. Action agencies are now performing this public service in some cases. A countervailing consideration is the burden this places upon the manpower of wildlife agencies.

4. The President's July 12, 1978, water policy directive stated:

> As part of their annual budget submissions, for each project in the planning or construction stage, Federal agencies will submit to the Office of Management and Budget reports which demonstrate compliance with the FWCA.

Although this reporting requirement may be formalized by an OMB circular, rather than in these rules, public comment is invited on the following:

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[1] It contended (in its statement contained in the brief filed by the United States) in *Hiram Hill* v. *TVA*, — U.S. — (1978), that a specific form of appropriations committee action is necessary to show that congressional appropriations constitute an authorization not otherwise granted by the Congress. This contention was adopted by the Supreme Court. Provided that these formal requirements are followed, it may make no difference whether appropriations, as opposed to authorizing, committees review and accept these proposals. The determination of which committee the matter should be assigned to is, of course, the prerogative of the Congress, but the manner in which the issue is brought to the attention of the Congress by the administration often predetermines the question.

Taking into account the difference in procedures and programs of project, licensing, and permit agencies, what aspects of FWCA compliance should be broken out for individual treatment in such reports?

5. *Should FWCA studies by wildlife agencies of proposed Federal or federally licensed projects be funded out of individual project funds?*

6. *What factors can or should be considered by action agencies in determining what wildlife conservation measures are justifiable to obtain maximum overall project benefits?*

7. *What procedures for FWCA consultation should be required among State and Federal wildlife agencies and action agencies?*

This notice of intent to propose rules is issued under authority of E.O. 12044, the FWCA, Pub. L. 85-624, 72 State. 563 (16 U.S.C. § 661 et seq. (1976)), and the Administrative Procedure Act, 5 U.S.C. § 552(a) (1976).

Issued this 22d day of September 1978.

RICHARD A. FRANK,
Administrator, National Oceanic and Atmospheric Administration, Department of Commerce.

DAVID F. HALES,
Acting Assistant Secretary of the Interior for Fish and Wildlife and Parks.

[FR Doc. 78-27584 Filed 9-28-78; 8:45 am]

notices

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

[3410-18]

DEPARTMENT OF AGRICULTURE

Economics, Statistics, and Cooperatives Service

ORGANIZATION, FUNCTIONS, AND AVAILABILITY OF INFORMATION

Notice is hereby given for the guidance of the general public as to the organization, functions, and availability of information for the Economics, Statistics, and Cooperatives Service (ESCS).

PART I—ORGANIZATION AND FUNCTION

Section 1—General. ESCS is an agency of the U.S. Department of Agriculture, and is the result of the consolidation of the Economic Research Service, the Statistical Reporting Service, the Farmer Cooperative Service, and the Economic Management Support Center. It was created on December 23, 1977 in response to Secretary's Memorandum No. 1927, of October 5, 1977, and No. 1927 Supplement 1 of December 19, 1977, entitled Reorganization of Selected Department Offices and Agencies. The specific delegations of authority from the Director of Economics, Policy Analysis and Budget to the Administrator ESCS are contained in 7 CFR 2.85.

Section 2—Organization. ESCS has its headquarters in Washington, D.C. In connection with economic research, a small staff is maintained in each of 36 States, principally at the Land Grant Colleges and Universities. Much of the research is carried out in cooperation with State agricultural experiment stations. In connection with statistical reporting, a State statistical office under the director or a statistician in charge is maintained in each of 44 States. In connection with cooperative activities, two employees are stationed in field locations.

The organization consists of the following:

Administrator
- Director, Information Staff
- Director, Program Evaluation and Development Staff

Deputy Administrator for Management
- Director, Administrative Services Division
- Director, Budget and Finance Division
- Director, Personnel Division

Deputy Administrator for Economics
- Director, Commodity Economics Division
- Director, National Economic Analysis Division
- Director, Economic Development Division
- Director, Natural Resource Economics Division
- Director, Foreign Demand and Competition Division
- Director, Data Services Center

Deputy Administrator for Statistics
- Director, Estimates Division
- Director, Statistical Research Division
- Director, Survey Division
- Director, State Statistical Division

Deputy Administrator for Cooperatives
- Director, Cooperative Marketing and Purchasing Division
- Director, Cooperative Management Division
- Director, Cooperative Development Division

Section 3—Authority to act for the Administrator. In the absence of the Administrator, the following officials are authorized to act for him in the order indicated:

Deputy Administrator for Statistics
Deputy Administrator for Economics
Deputy Administrator for Cooperatives
Deputy Administrator for Management

Section 4—Functions. ESCS has three major areas of responsibility:

(a) *Economic research.* Conduct economic and other social science research and analysis and provide public information relating to food and agriculture (nationally and internationally), natural resources, and rural people and communities in order to facilitate public and private decisionmaking. Specific functions include:

(1) Identify, measure, and explain interrelationships among economic forces, institutions, and alternative governmental policies and programs affecting nutritional well-being, food and fiber consumption and production, availability and use of natural resources, welfare of rural people and communities.

(2) Conduct research related to production, marketing, distribution, consumption, and foreign trade of food and fiber.

(3) Evaluate use, conservation, development, and control of water, land, and other natural resources as they affect economic growth, income distribution, and environmental quality.

(4) Conduct research related to rural people and communities, and their present and prospective economic adjustment problems.

(5) Make research and analytical findings available on a timely basis for use by public and private decisionmakers, including consumers, concerned with nutrition, food, agriculture, natural resources, rural people and communities.

(b) *Statistical reporting.* Carry out those broad statistical reporting and related functions of the Department which are assigned to ESCS. Specific functions include:

(1) Prepare crop and livestock estimates and administer reporting programs including estimates of production, supply, price, and other aspects of the U.S. agricultural economy and rural areas.

(2) Carry out the data collection and processing operations in connection with the crop and livestock estimating program of the Crop Reporting Board, including enumerative and objective measurement surveys.

(3) Prepare reports of the Crop Reporting Board of the Department of Agriculture covering official state and national estimates.

(4) Review, clear, and coordinate all statistical forms, survey plans, and reporting record keeping requirements originating in the Department and requiring approval of the Office of Management and Budget under the Federal Reports Act.

(5) Conduct programs involving: Research in methodology of agricultural data collection, estimation and forecasting, and special related research; surveys for other agenices; and improvement and coordination of statistics for the Department.

(c) *Cooperative activities.* Carry out economic research, analysis, technical assistance, and information programs relating to cooperatives in rural America. Specific functions include:

(1) Administer, coordinate, and implement current policies and programs to carry out broad research, technical assistance, educational, informational, developmental, and related functions and activities pertaining to cooperatives.

(2) Maintain, direct, and control applied research and technical assistance studies on cooperatives.

(3) Cooperate with Agencies in the Department and other Federal, State, and national organizations and institutions in developing and conducting programs affecting cooperatives.

(4) Design, implement, and coordinate a program to encourage develop-

ment of new cooperatives and expanded cooperative service.

(5) Desseminate research and educational materials to promote the principles, practices, and knowledge of cooperatives.

PART II—AVAILABILITY OF INFORMATION

Section 5—General. This part is issued in accordance with the regulations of the Secretary of Agriculture in part I, subpart A, of subtitle A of Title 7, CFR (7 CFR 1.1-1.16), and appendix A thereto, implementing the Freedom of Information Act (5 U.S.C. 552). The Secretary's regulations, as implemented by this part, govern the availability of records of ESCS to the public.

Section 6—Indexes. 5 U.S.C. 552(a)(2) requires that certain materials be made available for public inspection and copying and that a current index of these materials likewise be made available. ESCS does not maintain any materials within the scope of these requirements.

Section 7—Requests for records. Requests for records under 5 U.S.C. 552(a)(3) shall be made in accordance with 7 CFR 1.3(a) and addressed to: Chief, Records, Systems, and Analysis Branch, Administrative Services Division, Economics, Statistics, and Cooperatives Service, U.S. Department of Agriculture, Washington, D.C. 20250. Authority is hereby delegated to this official to make determination regarding such requests in accordance with 7 CFR 1.4(c).

Section 8—Appeals. Any person whose request for records is denied shall have the right to appeal that denial in accordance with 7 CFR 1.3(e) and 1.7. All appeals shall be addressed to: Administrator, Economics, Statistics, and Cooperatives Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Section 9—Requests for published data and related information. In Washington, D.C., published data and related information on all ESCS programs may be obtained from the director, Information Staff, Economics, Statistics, and Cooperatives Service, U.S. Department of Agriculture, Washington, D.C. 20250.

In the field, published data and related information on ESCS statistical programs will be made available for public inspection and copying by the statistician in charge at each State statistical office. Addresses for these State statistical offices are:

Alabama, 831 Arnov Bldg., 474 South Court St., Montgomery, Ala. 36104.
Alaska, Hillstrom Bldg. at Chugach and Fireweed Sts., Palmer, Alaska 99645.
Arizona, 3001 Federal Bldg., Phoenix, Ariz. 85025.
Arkansas, 362 U.S. Post Office Bldg., Little Rock, Ark. 72203.
California, 1220 North St., Room 243, Sacramento, Calif. 95814.
Colorado, 2490 West 26th Ave., Room 245, Denver, Colo. 80211.
Florida, 1222 Woodward St., Orlando, Fla. 32803.
Georgia, Federal Office Bldg., 355 East Hancock Ave., Athens, Ga. 30601.
Hawaii, State Department of Agriculture Bldg., 1428 South King St., Honolulu, Hawaii 96814.
Idaho, 304 North 8th St., Room 446, Boise, Idaho 83702.
Illinois, 218 Federal Bldg., Springfield, Ill. 62705.
Indiana, Agricultural Administration Bldg., Purdue University, West Lafayette, Ind. 47907.
Iowa, Federal Bldg., Room 855, 210 Walnut St., Des Moines, Iowa 50309.
Kansas, 444 Southeast Quincy, Topeka, Kans. 66683.
Kentucky, 446, U.S. Post Office Bldg., Louisville, Ky. 40202.
Louisana, U.S. Department of Agriculture Bldg., 3727 Government St., Alexandria, La. 71301.
Maryland, P.O. Box AG, College Park, Md. 20740 (includes Delaware).
Michigan, 201 Federal Bldg., Lansing, Mich. 48904.
Minnesota, Metro Square, Suite 270, 7th and Roberts St. St. Paul, Minn. 55101.
Mississippi, Executive Bldg., 401 Mississippi St., Jackson, Miss. 39205.
Missouri, 555 VanDiver Dr., Columbia, Mo. 65201.
Montana, Room 200 McGaffick Steamboat Block, Helena, Mont. 59601.
Nebraska, Room 273, 100 Centennial Mall North, Lincoln, Nebr. 68508.
Nevada, Max C. Fleischmann Agriculture Bldg., Room 232, Reno, Nev. 89507.
New England, Room 522 Federal Bldg., 55 Pleasant St., Concord, N.H. 03301.
New Jersey, Health and Agriculture, Room 204, John Fitch Plaza, Trenton, N.J. 08625.
New Mexico, Room C 203, Second Flood, Federal Bldg. and U.S. Court House, Griggs Ave. at Church St., Las Cruces, N. Mex. 88001.
New York, Department of Agriculture and Markets, State Campus, Bldg. 8, Room 800, Albany, N.Y. 12235.
North Carolina, 216 West Jones St., Raleigh, N.C. 27611.
North Dakota, New Federal Bldg., Room 345, Fargo, N. Dak. 58102.
Ohio, New Federal Bldg., Room 608, Spring and High Sts., Columbus, Ohio 43215.
Oklahoma, 523 Old Post Office Bldg., Oklahoma City, Okla. 73102.
Oregon, 1735 Federal Bldg., 1220 Southwest Third Ave., Portland, Oreg. 97204.
Pennsylvania, Pennsylvania Crop Reporting Service, Room G-19, 2301 North Cameron St., Harrisburg, Pa. 17120.
South Carolina, 240 Stoneridge Rd., Columbia, S.C. 29210.
South Dakota, P.O. Drawer V, 3528 South Western Ave., Sioux Falls, S. Dak. 57101.
Tennessee, U.S. Court House, Room 697, 8th and Broadway, Nashville, Tenn. 37203.
Texas, 555 Federal Bldg., 300 East 8th St., Austin, Tex. 78701.
Utah, 4432 Federal Bldg., 125 South State St., Salt Lake City, Utah 84147.
Virginia, 203 North Governor St., Room 312, Richmond, Va. 23219.
Washington, 3039 Federal Office Bldg., 909 First Ave., Seattle, Wash. 98174.
West Virginia, State Department of Agriculture, Charleston, W.Va. 25305.
Wisconsin, 801 West Badger Rd., Madison, Wis. 53713.
Wyoming, Post Office and Court House Bldg., Room 7008, Cheyenne, Wyo. 82001.

Dated: September 25, 1978.

KENNETH R. FARRELL,
Administrator.

[FR Doc. 78-27459 Filed 9-28-78; 8:45 am]

[3410-10]

Office of the Secretary

MEAT IMPORT LIMITATIONS

Fourth Quarterly Estimate

Pub. L. 88-482, approved August 22, 1964 (hereinafter referred to as the Act), provides for limiting the quantity of fresh, chilled, or frozen cattle meat (TSUS 106.10) and fresh, chilled, or frozen meat of goats and sheep, except lamb (TSUS 106.20), which may be imported into the United States in any calendar year. Such limitations are to be imposed when it is estimated by the Secretary of Agriculture that imports of such articles, in the absence of limitations during such calendar year, would equal or exceed 110 percent of the estimated quantity of such articles, prescribed by section 2(a) of the Act.

In accordance with the requirements of the Act, the following fourth quarterly estimates for 1978 are published.

1. The estimated aggregate quantity of such articles which would, in the absence of limitations under the Act, be imported during calendar year 1978 is 1,492.3 million pounds.

2. The estimated aggregate quantity of such articles prescribed by section 2(a) of the Act during the calendar year 1978 is 1,183.9 million pounds.

Since the estimated quantity of imports continues to exceed 110 percent of the estimated quantity prescribed by section 2(a) of the Act, limitations for the calendar year 1978 on the importation of fresh, chilled, or frozen cattle meat (TSUS 106.10) and fresh, chilled, or frozen meat of goats and sheep (TSUS 106.20) are required unless suspended by the president pursuant to section 2(d) of Pub. L. 88-482. Such limitations were imposed by Proclamation 4577 of July 4, 1978, but were suspended during the balance of the calendar year 1978.

Done at Washington, D.C., this 26th day of September 1978.

CAROL TUCKER FOREMAN,
Acting Secretary.

[FR Doc. 78-27514 Filed 9-28-78; 8:45 am]

[6320-01]

CIVIL AERONAUTICS BOARD

[Docket No. 33091]

FLORIDA SERVICE CASE

Further Postponement of Prehearing Conference

Notice is hereby given that the prehearing conference in the above-entitled matter now assigned to be held on October 11, 1978 (43 FR 36499, Aug. 17, 1978; 43 FR 40254, Sept. 11, 1978; 43 FR 43051, Sept. 22, 1978) is hereby further postponed to October 12, 1978 at 10 a.m. (local time) in room 1003, hearing room D, Universal Building North, 1875 Connecticut Avenue NW., Washington, D.C.

Dated at Washington, D.C., September 25, 1978.

WILLIAM H. DAPPER,
Administrative Law Judge.

[FR Doc. 78-27585 Filed 9-28-78; 8:45 am]

[6320-01]

[Docket No. 21670]

FRONTIER AIRLINES, INC., SUBSIDY MAIL RATES

Notice of Oral Argument

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that oral argument in this proceeding is assigned to be held before the Board on November 1, 1978, at 10 a.m. (local time), in room 1027, Universal Building, 1825 Connecticut Avenue NW., Washington, D.C.

Each party which wishes to participate in the oral argument shall so advise the Secretary, in writing, on or before October 13, 1978, together with the name of the person who will represent it at the argument.

Dated at Washington, D.C., September 20, 1978.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-27586 Filed 9-28-78; 8:45 am]

[6320-01]

[Docket No. 32376]

SAN ANTONIO-DENVER ROUTE PROCEEDING

Notice of Hearing

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a hearing in the above-entitled proceeding will be held commencing on October 24, 1978, at 10 a.m. (local time) in the VIP room, Henry B. Gonzales Convention Center, Market and Alamo Streets, San Antonio, Tex., before the undersigned administrative law judge.

For information concerning the issues involved and other details in this proceeding, interested persons are referred to the prehearing conference report, served on June 28, 1978, and other documents which are in the docket of this proceeding on file in the docket section of the Civil Aeronautics Board.

Dated at Washington, D.C., September 25, 1978.

KATHERINE A. KENT,
Administrative Law Judge.

[FR Doc. 78-27587 Filed 9-28-78; 8:45 am]

[6320-01]

[Docket No. 32126]

TWIN CITIES-KANSAS CITY-OKLAHOMA-TEXAS ROUTE PROCEEDING

Postponement of Hearing

Notice is given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that the hearing in the above-entitled proceeding, which is assigned to be held on October 10, 1978 (43 FR 35090, Aug. 8, 1978), is postponed to November 14, 1978, at 10 a.m. (local time), in room 1003, hearing room C, Universal North Building, 1875 Connecticut Avenue NW., Washington, D.C.

Dated at Washington, D.C., September 25, 1978.

ALEXANDER N. ARGERAKIS,
Administrative Law Judge.

[FR Doc. 78-27588 Filed 9-28-78; 8:45 am]

[6335-01]

CIVIL RIGHTS COMMISSION

HEARING

Notice is hereby given pursuant to provisions of the Civil Rights Act of 1957, 71 Stat. 634, as amended, that a public hearing of the U.S. Commission on Civil Rights will commence on October 31, 1978 at Commerce Auditorium, Main Commerce Building, 14th and Consitution Avenue NW., Washington, D.C. 20230. An executive session, if appropriate, may be convened at any time before or during the hearing.

The purpose of the hearing is to collect information concerning legal developments constituting a denial of equal protection of the laws under the Constitution because of race, color, religion, sex, or national origin, or in the administration of justice, particularly concerning the administration and enforcement of the immigration and nationality laws of the United States; to appraise the laws and policies of the Federal Government with respect to denials of equal protection of the laws under the Constitution because of race, color, religion, sex, or national origin, or in the administration of justice, particularly concerning the administration and enforcement of the immigration and nationality laws of the United States; and to disseminate information with respect to denials of equal protection of the laws under the Constitution because of race, color, religion, sex, or national origin, or in the administration of justice, particularly concerning the administration and enforcement of the immigration and nationality laws of the United States.

Dated at Washington, D.C., September 25, 1978.

ARTHUR S. FLEMMING,
Chairman.

[FR Doc. 78-27634 Filed 9-28-78 8:45 am]

[3510-25]

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket No. 12-78]

FOREIGN-TRADE ZONES AND SUBZONES—GREATER CINCINNATI AREA

Application and Public Hearing

Notice is hereby given that an application has been submitted to the Foreign-Trade Zones Board (the Board) by the Greater Cincinnati Foreign-Trade Zone, Inc. (GCFTZ), a nonprofit Ohio corporation, requesting authority to establish general-purpose foreign-trade zones in the Cincinnati port of entry area, at sites in Ohio and Kentucky. It also requests three special-purpose subzones in the Cincinnati port of entry area and another adjacent to the Columbus, Ohio, port of entry.

The application, which was formally filed on September 19, 1978, was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). The applicant is a nonprofit affiliate of the Greater Cincinnati Chamber of Commerce organized to apply for and establish foreign-trade zone facilities. Its authority to make the application is House Bill 200, 1977 Laws of Ohio (effective Aug. 26, 1977). The GCFTZ has been delegated authority to apply for zone sites in Kentucky by the Northern Kentucky Port Authority, an agency authorized to apply for zones in Kentucky under section 65.530 (6) of the Kentucky Revised Statutes.

The Ohio general-purpose zone facilities would be situated on two sites, of 5.6 acres and 95.2 acres, located some 25 miles north of Cincinnati in the southern portion of Butler

County, to be developed and operated by the W. P. Butler Co.

The Kentucky general-purpose zone is to be located at two separate sites in Campbell County, about 10 miles south of Cincinnati. One would consist of a warehouse facility located on a 1.2-acre tract in Wilder, Ky., to be operated by H. J. Hosea and Sons Co., Inc. The other Kentucky site would be established on a 17-acre tract within the E. J. Knepfle Industrial Park, a site being developed by the Northern Kentucky Port Authority as part of a riverport development project.

The application contains economic data and information concerning the need for providing zone services to business firms in the greater Cincinnati area: Several firms have indicated their intention to use the general-purpose zones for warehousing, assembly, packaging, testing, and processing activities. The products involved would include industrial machinery, vacuum cleaners, conveyor parts, industrial knives, rainwear, alcoholic beverages, footwear, and machine tools.

The three Cincinnati area subzones would be established at existing facilities of the following: Cincinnati Electronics Corp., 260 Glendale-Milford Road, Hamilton County, Ohio (31.5 acres for operations involving components for airborne and vehicular UHF and VHF communications equipment, coding missiles, antennas, and airborne radar systems); Emery Industries, Inc., 4900 Este Avenue, Cincinnati (62 acres for operations involving the manufacture of specialty chemicals mostly for export); and the General Electric Co. (Evendale), I-75 and Jimson Road, Hamilton County (two buildings of over 400,000 square feet for operations involving the testing of imported engines used in aircraft produced for export).

The other proposed subzone is being requested by GCFTZ in cooperation with the State of Ohio Department of Economic and Community Development for Honda of America. Honda is developing a 214-acre tract on U.S. Route 33 in Allen Township, Union County. Subzone status is being requested for the entire tract which will initially house a 258,400-square-foot motorcycle assembly plant. The second phase of development of the subzone would include an auto assembly operation.

In accordance with the Board's regulations, an Examiners Committee has been appointed to investigate the application and report thereon to the Board. The Committee consists of: Hugh J. Dolan (Chairman), Office of the Secretary, U.S. Department of Commerce, 14th and E Streets NW., Washington, D.C. 20230; Donald L. Cavanaugh, District Director, U.S. Customs Service, 55 Erieview Plaza (sixth floor, Plaza 9 Building), Cleveland, Ohio 44114; and Col. Thomas P. Nack, District Engineer, U.S. Army Engineer District Louisville, P.O. Box 59, Louisville, Ky. 40201.

As part of its investigation of the proposal, the Examiner Committee will hold a public hearing on October 19, 1978, beginning at 9 a.m., in the second floor presentation room of the Greater Cincinnati Chamber of Commerce, Fifth and Race Streets Tower, 120 West Fifth Street, Cincinnati, Ohio. The purpose of the hearing is to help inform interested persons about the proposal, to provide an opportunity for their expression of views, and to obtain information useful to the examiners.

Interested persons or their representatives are invited to present their views at the hearing. Such persons should, by October 13, notify the Board's executive secretary of their desire to be heard in writing at the address below or by phone 202-377-2862. In lieu of an oral presentation, written statements may be submitted in accordance with the Board's regulations to the Examiners Committee, care of the executive secretary, at any time from the date of this notice through November 20, 1978. Evidence submitted during the post-hearing period is not desired unless it is clearly shown that the matter is new and material and that there are good reasons why it could not be presented at the hearing. A copy of the application and accompanying exhibits will be available during this time for public inspection at each of the following locations:

Office of the Director, U.S. Department of Commerce District Office, 10504 Federal Office Building, 550 Main Street, Cincinnati, Ohio 45202.

Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 6886-B, Washington, D.C. 20230.

Dated: September 26, 1978.

JOHN J. DA PONTE, Jr.,
Executive Secretary,
Foreign-Trade Zones Board.

[FR Doc. 78-27500 Filed 9-28-78; 8:45 am]

[3510-25]

Foreign-Trade Zones Board

[Docket No. 11-78]

FOREIGN-TRADE ZONE—BOONVILLE, MO.

Application and Public Hearing

Notice is hereby given that an application has been submitted to the Foreign-Trade Zones Board (the Board) by the Greater Kansas City Foreign-Trade Zone, Inc., a not-for-profit Missouri corporation and grantee of Foreign-Trade Zones No. 15 and No. 17 in the Greater Kansas City area, requesting a grant of authority to establish a foreign-trade zone at Boonville, Mo., adjacent to the Kansas City, Mo., customs port of entry. The application was submitted pursuant to the provisions of he Foreign-Trade Zones Act, as amended (19 U.S.C. 81a-81u), and the regulations of the Board (15 CFR Part 400). It was formally filed on September 19, 1978. The applicant is authorized to make this proposal under Missouri Senate bill No. 135, 78th General Assembly.

The proposal calls for a foreign-trade zone of 2.55 acres, located within the city limits of Boonville, Mo., in an industrial development area. It will be operated by the Howard-Cooper County Regional Port Authority of Boonville. The zone site is served by highway and rail and is about 4 miles from the operator's barge terminal site on the Missouri River. A 25,000 square foot warehouse-type building will be the zone's first structure.

The application contains economic data and information concerning the need for zone services in the Boonville area. Several firms have indicated their intention to use the zone for storage, processing, packaging and distribution. Among the initial zone users are firms involved in products including lumber, phosphates, bulk, cement, wines and liquors, fence wire, twine, rope, slate, and agricultural grains.

In accordance with the Board's regulations, an Examiners Committee has been appointed to investigate the application and report thereon to the Board. The Committee consists of: Hugh J. Dolan (Chairman), Office of the Secretary, U.S. Department of Commerce, 14th and E Streets NW., Washington, D.C. 20230; William L. Duncan, District Director, U.S. Customs Service, 120 S. Central Avenue, Suite 408, Chromalloy Building, St. Louis, Mo. 63105; and Col. Walter C. Bell, District Engineer, U.S. Army Engineer District Kansas City, 700 Federal Building, Kansas City, Mo. 64106.

As part of its investigation of the proposal, the Examiners Committee will hold a public hearing on October 17, 1978, beginning at 9 a.m., in the Council Chambers of the Boonville Municipal Building, Spring and Sixth Streets, Boonville, Mo. The purpose of the hearing is to help inform interested persons about the proposal, to provide an opportunity for their expression of views, and to obtain information useful to the examiners.

Interested persons or their representatives are invited to present their views at the hearing. Such persons should, by October 10, notify the Board's executive secretary of their desire to be heard, in writing at the address below or by phone 202-377-2862. In lieu of an oral presentation, written statements may be submitted

in accordance with the Board's regulations to the Examiners Committee, care of the executive secretary, at any time from the date of this notice through November 16, 1978. The submission of evidence is not desired during the post-hearing period unless it is clearly shown that the matter is new and material and that there are good reasons why it could not be presented at the hearing. A copy of the application and accompanying exhibits will be available during this time for public inspection at each of the following locations:

Office of the Port Director, U.S. Customs Service, 2701 Rockcreek Parkway, Suite 202, North Kansas City, Mo. 64116.
Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, Room 6886-B, 14th and E Streets, NW., Washington, D.C. 20230.

Dated: September 26, 1978.

JOHN J. DA PONTE, Jr.,
Executive Secretary.

[FR Doc. 78-27501 Filed 9-28-78; 8:45 am]

[6820-33]

COMMITTEE FOR PURCHASE FROM BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1978

Proposed Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed additions to procurement list.

SUMMARY: The Committee has received proposals to add to Procurement List 1978 commodities to be produced by and a service to be provided by workshops for the blind or other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: November 1, 1978.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Va. 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, 703-557-1145.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2), 85 Stat. 77.

If the Committee approves the proposed additions, all entities of the Federal Government will be required to procure the commodities and the service listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodities and service to Procurement List 1978, November 14, 1977 (42 FR 59015):

Class 7510: Binder, Awards Certificate (IB), 7510-00-056-1927.
Class 6230: Light marker, distress (SH), 6230-00-892-5192.
SIC 0782: Grounds maintenance (SH), quarters "A", nonindustrial area, Naval Ordnance Station, Indianhead, Md.

C. W. FLETCHER,
Executive Director.

[FR Doc. 78-27456 Filed 9-28-78; 8:45 am]

[6820-33]

PROCUREMENT LIST 1978

Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Addition to procurement list.

SUMMARY: This action adds to Procurement List 1978 commodities to be produced by workshops for the blind or other severely handicapped.

EFFECTIVE DATE: September 29, 1978.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Va. 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher, 703-557-1145.

SUPPLEMENTARY INFORMATION: On May 5, 1978 the Committee for Purchase from the Blind and Other Severely Handicapped published notice (43 FR 19430) of proposed addition to Procurement List 1978, November 14, 1977 (42 FR 59015).

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46-48c 85 Stat. 77.

Accordingly, the following commodities are hereby added to Procurment List 1978:

Class 1730: Chock Assembly, Wheel (IB)
1730-00-NIB-001A, 2" × 4" × 8".
1730-00-NIB-001B, 6" × 8" × 18".
1730-00-NIB-001C 6" × 8" × 76".
1730-00-NIB-001D, 8" × 12" (U-shaped).
1730-00-NIB-001E, 10" × 20" (U-shaped).

C. W. FLETCHER,
Executive Director.

[FR Doc. 78-27457 Filed 9-28-78; 8:45 am]

[3710-08]

DEPARTMENT OF DEFENSE

Department of the Army

STATIONING OF THE INITIAL BATTALION OF 2D INFANTRY DIVISION

Invitation for Public Comment

Notice is hereby given that the Department of the Army, in accordance with Department of Defense policy, invites public comment on the proposed interim stationing of the 2d Battalion/9th Infantry of the 2d Infantry Division to be withdrawn from Korea.

On September 18, 1978, the Secretary of the Army made the following announcement:

The Secretary of the Army today announced plans for stationing the first units to be withdrawn from Korea under the plan announced last year by the President. These units, the 2d Battalion/9th Infantry of the 2d Infantry Division and the 833d Ordnance Company, are scheduled to leave Korea in December 1978. Because a decision on the permanent stationing of the 2d Infantry Division has been delayed, the infantry battalion will be temporarily stationed. Fort Riley, Kans., has been selected as the preferred alternative for the temporary stationing of the infantry battalion subject to the completion and evaluation of the results of appropriate environmental documentation. Environmental documentation has been completed for the ordnance company stationing and it has been decided that Seneca Army Depot, N.Y., will be the permanent base of this unit. This company, a nondivisional unit, is not a part of the 2d Infantry Division.

In order to accommodate the infantry battalion (approximate strength 500 men), the Army has conducted an analysis of division and other tactical unit installations which are not under primary consideration as part of the study of the permanent stationing of the 2d Infantry Division in the United States. As has been previously announced, four options are currently being reviewed as part of that stationing study. These options are Forts Bliss, Benning, and Drum as separate installations and a combination of Forts Dix, Devens, and Drum. Additional time will be required to make a final decision on the permanent stationing of the 2d Infantry Division in the United States.

In arriving at Fort Riley as the preferred alternative, the interim stationing analysis for the infantry battalion considered sufficiency of temporary barracks, availability of housing, adequacy of training facilities, and compatibility of a parent headquarters. Forts Carson, Colo.; Lewis, Wash.; Polk, La.; Riley, Kans.; Stewart, Ga.; Knox, Ky.; Hood, Tex.; Bragg, N.C.; Campbell, Ky.; Ord, Calif.; Richardson, Alaska; Wainwright, Alaska; and Schofield Barracks, Hawaii, were considered in this analysis.

Fort Riley, Kans., the preferred alternative for interim stationing of the infantry battalion, has over 3,200 temporary barracks spaces, most of which are used for ROTC summer camp and Reserve component training. These barracks could accommodate on a temporary basis the calendar year (CY) 1978 2d Infantry Division battalion being withdrawn from Korea, but may

require the relocation of all or part of ROTC and Reserve component training to other Active Army bases. The selection of Fort Riley as the preferred alternative is consistent with the long-term stationing objectives of the Army.

Comments should be furnished to Headquarters, Department of the Army, Attention: DAMO-ODU, Washington, D.C. 20310, by October 20, 1978. Comments submitted to Department of the Army by the close of the public comment period will be considered, as appropriate, in the decision-making process which may be completed as early as November 1, 1978.

R. D. RENICK, Jr.,

Brigadier General, GS, Deputy Director of Operations and Readiness.

[FR Doc. 78-27452 Filed 9-28-78; 8:45]

[3810-70]

Office of the Secretary

DEFENSE SYSTEMS MANAGEMENT COLLEGE

Board of Visitors Meeting

A meeting of the Board of Visitors of the Defense Systems Management College will be held in Building 202, Fort Belvoir, Va., on Wednesday, November 15, 1978, from 8:30 a.m. until 5 p.m. The agenda will include a review of plans, resources, and course offerings and a general discussion of DSMC operations. The meeting is open to the public; however, because of limitations on space available, allocation of seating will be made on a first come, first served basis. Persons desiring to attend should call the DSMC Director, Department of Administration and Operational Support, 703-664-1175, to reserve a seat.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Service, Department of Defense.

SEPTEMBER 26, 1978.

[FR Doc. 78-27495 Filed 9-28-78; 8:45 am]

[3128-01]

DEPARTMENT OF ENERGY

Economic Regulatory Administration

DOMESTIC CRUDE OIL ALLOCATION PROGRAM

Entitlement notice for July 1978

AGENCY: Department of Energy, Economic Regulatory Administration.

ACTION: July 1978 entitlement Notice.

SUMMARY: Under the Department of Energy's (DOE) domestic crude oil allocation (entitlements) program, this is the monthly entitlement notice which sets forth the entitlement purchase or sale requirements of domestic refiners for July 1978.

DATES: Payments for entitlements required to be purchased under this notice must be made by September 30, 1978. The monthly transaction report specified in § 211.61(i) shall be filed with the DOE by October 10, 1978.

FOR FURTHER INFORMATION CONTACT:

Douglas McIver (Entitlements Program Office), Economic Regulatory Administration, 2000 M Street NW., Room 6128I, Washington, D.C. 20461, 202-254-8660.

Fred Wolgel (Office of General Counsel), Department of Energy, 12th and Pennsylvania Avenue NW., Room 7134, Washington, D.C. 20461, 202-566-2454.

SUPPLEMENTAL INFORMATION: In accordance with the provisions of 10 CFR 211.67 relating to the domestic crude oil allocation program of the Department of Energy (DOE), administered by the Economic Regulatory Administration (ERA), the monthly notice specified in § 211.67(i) is hereby published.

Based on reports for July 1978 submitted to the DOE by refiners and other firms as to crude oil receipts, crude oil runs to stills, eligible product imports and imported naphtha utilized as a petrochemical feedstock in Puerto Rico; application of the entitlement adjustment for residual fuel oil production for sale in the east coast market provided in § 211.67(d)(4); application of the entitlement adjustments for California lower-tier and upper-tier crude oil provided in § 211.67(a)(4); August 1978 deliveries of crude oil for storage in the strategic petroleum reserve; and application of the entitlement adjustment for small refiners provided in § 211.67(e), the national domestic crude oil supply ratio for July 1978 is calculated to be 0.183606.

In accordance with § 211.67(b)(2), to calculate the number of barrels of deemed old oil included in a refiner's adjusted crude oil receipts for the month of July 1978, each barrel of old oil is equal to one barrel of deemed old oil and each barrel of upper-tier crude oil is equal to 0.183257 of a barrel of deemed old oil.

The issuance of entitlements for the month July 1978 to refiners and other firms is set forth in the appendix to this notice. The appendix lists the name of each refiner or other firm to which entitlements have been issued, the number of barrels of deemed old oil included in each such refiner's adjusted crude oil receipts, the number of entitlements issued to each such refiner or other firm, and the number of entitlements required to be purchased or sold by each such refiner or other firm.

Pursuant to 10 CFR 211.67(i)(4), the price at which entitlements shall be sold and purchased for the month of July 1978 is hereby fixed at $8.16, which is the exact differential as reported for the month of July between the weighted average per barrel costs to refiners of old oil and of imported and exempt domestic crude oil, less the sum of 21 cents.

In accordance with 10 CFR 211.67(b), each refiner that has been issued fewer entitlements for the month of July 1978 than the number of barrels of deemed old oil included in its adjusted crude oil receipts is required to purchase a number of entitlements for the month of July 1978 equal to the difference between the number of barrels of deemed old oil included in those receipts and the number of entitlements issued to and retained by that refiner. Refiners which have been issued a number of entitlements for the month of July 1978 in excess of the number of barrels of deemed old oil included in their adjusted crude oil receipts for that month and other firms issued entitlements shall sell such entitlements to refiners required to purchase entitlements. In addition, certain refiners are required to purchase or sell entitlements to effect corrections for reporting errors for the months September 1975 through June 1978 pursuant to 10 CFR 211.67(j)(1).

The listing of refiners' old oil receipts contained in the appendix reflects any adjustments made by ERA pursuant to § 211.67(h).

The listing contained in the appendix identifies in a separate column labeled "Exceptions and Appeals" additional entitlements issued to refiners pursuant to relief granted by the Office of Hearings and Appeals (prior to Mar. 30, 1978 the Office of Administrative Review of the Economic Regulatory Administration). Also set forth in this column are adjustments for relief granted by the Office of Hearings and Appeals for 1975 and 1976, which adjustments are reflected in monthly installments. The number of installments is dependent on the magnitude of the adjustment to be made. For a full discussion of the issues involved, *see Beacon Oil Company, et al.*, 4 FEA par. 87,024 (Nov. 5, 1976).

The listing contained in the appendix continues the "Consolidated Sales" entry initiated in the October 1977 entitlement notice. The "Consolidated Sales" entry is equal to the July 1978 entitlement purchase require-

ment of Arizona Fuels. The purpose of providing for the "Consolidated Sales" entry is to insure that Arizona Fuels is not relieved of its July 1978 entitlement purchase requirement and that no one firm will be unable to sell its entitlements by reason of a default by Arizona Fuels. For a full discussion of the issues involved, *see Entitlement Notice for October 1977* (42 FR 64401, Dec. 23, 1977).

For purposes of § 211.67(d) (6) and (7), which provide for entitlement issuances to refiners or other firms for sales of imported crude oil to the U.S. Government for storage in the strategic petroleum reserve, the number of barrels sold to the Government totaled 8,405,114 barrels.

For purposes of the adjustments to refiners' crude run volumes under § 211.67(d)(4), total production of residual fuel oil for sale in the east coast market (in excess of the first 5,000 barrels per day thereof for each refiner reporting such production) was 12,045,603 barrels for July 1978. For that month, imports of residual fuel oil eligible for entitlements issuances totaled 32,800,587 barrels.

On June 15, 1978, we issued a notice of proposed rulemaking which proposed certain changes to the entitlements program with respect to imported residual fuel, such changes to be effective July 1, 1978 (43 FR 26551, June 20, 1978). If the proposed changes are adopted, we will make the necessary adjustments in the first entitlement notice following promulgation of the final rule.

In accordance with § 211.67(a)(4), the number of barrels of California lower-tier and upper-tier crude oil as reported by refiners to the DOE, and the weighted average gravity thereof are as follows:

	Volumes	Weighted average gravity (degrees)
California lower-tier crude oil	9,489,111	19
California upper-tier crude oil	7,022,026	19

The total number of entitlements required to be purchased and sold under this notice is 21,441,959.

Based on reports submitted to the DOE by refiners as to their adjusted crude oil receipts for July 1978, the pricing composition and weighted average costs thereof are as follows:

	Volumes	Weighted average cost	Percent of total volumes [1]
Lower tier	90,973,165	$5.96	18.6
Upper tier	90,848,071	12.62	18.6
Exempt domestic:			
Alaskan	33,379,454	13.13	6.8
Stripper	36,821,514	14.43	7.5
Naval petroleum reserve	2,901,386	13.53	0.6
Total domestic	254,923,590	10.56	52.1
Imported	233,994,623	14.49	47.9
Total reported crude oil receipts	488,918,215	12.45	100.0
Total reported crude oil runs to stills	493,865,027		

[1] Numbers may not add due to rounding.

Payment for entitlements required to be purchased under 10 CFR 211.67(b) for July 1978 must be made by September 30, 1978.

On or prior to October 10, 1978, each firm which is required to purchase or sell entitlements for the month of July 1978 shall file with the DOE the monthly transaction report specified in 10 CFR 211.66(i) certifying its purchases and sales of entitlements for the month of July. The monthly transaction report forms for the month of July have been mailed to reporting firms. firms that have been unable to locate other firms for required entitlement transactions by September 30, 1978 are requested to contact the ERA at 202-254-3336 to expedite consummation of these transactions. For firms that have failed to consummate requred entitlement transactions on or prior to September 30, 1978, the ERA may direct sales and purchases of entitlements pursuant to the provisions of 10 CFR 211.67(k).

This notice is issued pursuant to Subpart G, 10 CFR Part 205. Any person aggrieved hereby may file an appeal with the Office of Hearings and Appeals in accordance with Subpart H of 10 CFR Part 205. Any such appeal shall be filed on or before October 30, 1978.

Issued in Washington, D.C., on September 24, 1978.

DAVID J. BARDIN,
Administrator, Economic Regulatory Administration.

[FR Doc. 78-27365 Filed 9-26-78; 8:45 am]

APPENDIX
NOTICE OF ENTITLEMENTS FOR DOMESTIC CRUDE OIL

JULY 1978

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
*CONSOLID*SALES	-147,795	0	0	0	0	0	147,795*
A*JOHNSON	0	140,536	0	0	0	0	140,536
ALLIED	99,434	87,084	0	0	0	12,350	0
AMEX*PETROFINA	933,441	863,067	0	0	0	70,374	0
AMERADA*HESS	2,121,261	2,871,226	0	83,001	0	0	749,965
AMOCO	9,059,369	6,074,031	0	10,458	0	2,985,338	0
ANCHOR	2,719	91,259	0	0	2,565	0	88,540
ARCO	3,234,438	4,210,249	0	0	97,178	0	973,811
ARIZONA	234,410	86,615	6,145	0	2,523	147,795	0
ASAMERA	75,729	159,269	0	0	0	0	83,540
ASHLAND	1,264,417	2,002,921	0	0	0	0	738,504
ASIATIC	0	178,649	0	178,649	0	0	178,649
BASIN	247,450	196,300	0	0	81,486	51,150	0
BAYOU	47,460	59,784	0	0	0	0	12,324
BEACON	214,321	258,899	84,917	0	36,054	0	44,578
BELCHER	0	49,603	0	49,603	0	0	49,603
BI*PETRO	7,449	135,815	0	0	0	0	128,366
BP*TRADING	0	356,365**	0	0	0	0	356,365
BRUIN	35,466	127,732	0	0	0	0	92,266
C&H	86	198	0	0	0	0	112
CALCASIEU	9,601	63,991	0	0	0	0	54,390
CALUMET	20,583	29,296	0	0	0	0	8,713
CANAL	70,015	76,784	0	0	0	0	6,769
CARIBOU	88,725	96,427	0	0	0	0	7,702
CHAMPLIN	1,103,732	1,381,354	0	0	239,943	0	277,622
CHARTER	725,208	910,709	470,935	0	0	0	185,501
CHEVRON	5,678,509	6,902,134	0	46,130	266,418	0	1,223,625
CIRILLO	0	18,006	0	18,006	0	0	18,006
CITGO	2,093,305	1,400,539	0	0	0	692,766	0
CLAIBORNE	77,149	46,923	0	0	0	30,226	0
CLARK	204,619	686,235	0	0	0	0	481,616
COASTAL	224,885	1,376,051	0	29,645	0	0	1,151,166
COLONIAL	0	11,221	0	11,221	0	0	11,221
CONOCO	2,539,014	2,193,502	0	7,083	163,276	345,512	0
CORCO	0	1,048,606	177,186***	203,789	0	0	1,048,606
CRA*FARMLAND	348,086	480,698	0	0	0	0	132,612
CROSS	48,622	105,455	0	0	0	0	56,833
CROWN	340,192	608,304	0	0	0	0	268,112
CRYSTAL*OIL	121,264	163,206	0	0	0	0	41,942
CRYSTAL*REF	9,152	32,122	0	0	0	0	22,970
DELTA	210,360	312,221	0	0	0	0	101,861
DEMENNO	5,007	75,603	0	0	5,022	0	70,596
DERBY	0	400,149**	0	0	0	0	400,149
DIAMOND	497,713	350,450	0	0	0	147,263	0
DILLMAN	0	2,435	0	0	0	0	2,435
DONCHESTER	40,677	555,046	337,105	0	0	0	514,369
DOW	90,224	97,628	0	0	0	0	7,404
E*SEABOARD	0	30,743	0	30,743	0	0	30,743
ECO	73,935	84,172	0	0	23,214	0	10,237
EDDY	43,139	43,035	0	0	0	104	0
ELM	0	6,736	0	6,736	0	0	6,736
ENERGY*COOP	0	765,895	0	0	0	0	765,895
ERICKSON	209	132,602	0	0	0	0	132,393
EVANGELINE	37,741	40,407	0	0	0	0	2,666
EXXON	8,520,338	7,881,177**	0	308,805	0	639,161	0
EZ*SERVE	12,890	38,780	0	0	20	0	25,890
FARMERS*UN	264,496	306,407	0	0	0	0	41,911
FLETCHER	2,981	182,990	0	0	341	0	180,009
FLINT	6,762	8,747	0	0	0	0	1,985
GARY	70,683	88,911	0	0	0	0	18,228
GETTY	960,518	971,643	0	0	0	0	11,125
GIANT	34,817	59,385	0	0	0	0	24,568
GLACIER*PARK	99,065	49,574	0	0	0	49,491	0
GLADIEUX	32,289	79,226	0	0	0	0	46,937

NOTICE OF ENTITLEMENTS FOR DOMESTIC CRUDE OIL

JULY 1978

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
GLENROCK	1,739	3,155	0	0	0	0	1,416
GOLDEN-EAGLE	0	149,839	0	0	0	0	149,839
GOLDEN-EAGLE-NY	0	2,613	0	2,613	0	0	2,613
GOLDKING	76,202	129,582	0	0	0	0	53,380
GOOD-HOPE	43,657	267,385	0	0	0	0	223,728
GUAM	0	273,726	0	0	0	0	273,726
GULF	6,990,363	4,511,368	0	21,471	67,595	2,478,995	0
GULF-BTS	16,539	126,333	0	0	0	0	109,794
HINI	0	415,705	0	0	0	0	415,705
HOWELL	120,543	219,535	0	0	0	0	98,992
HUDSON-OIL	11,909	185,896	0	0	0	0	173,987
HUNT	121,944	137,745	0	0	0	0	15,801
HUSKY	548,875	548,875	234,241	0	0	0	0****
INDEPENDENT-REF	95,072	131,759	0	0	0	0	36,687
INDIANA-FARM	35,424	186,104	0	0	0	0	150,680
IRVING	0	11,705	0	11,705	0	0	11,705
J&W	50,622	52,093	0	0	0	0	1,471
KENCO	17,470	34,170	0	0	0	0	16,700
KENTUCKY	15,164	13,284	0	0	0	1,880	0
KERN	404,181	425,593	168,243	0	56,317	0	21,412
KERR-MCGEE	1,034,314	860,296	0	0	0	174,018	0
KOCH	225,924	716,017	0	13,756	0	0	490,093
LAGLORIA	437,444	254,311	0	0	0	183,133	0
LAKESIDE	24,003	27,254	0	0	0	0	3,251
LAKETON	125,659	153,788	37,396	0	0	0	28,129
LITTLE-AMER	1,274,591	957,257	517,090	0	0	317,334	0
LOUISIANA-LAND	200,598	289,861	0	0	0	0	89,263
MACMILLAN	36,398	150,509	0	0	4,278	0	114,111
MARATHON	4,486,243	2,890,232	0	0	0	1,596,011	0
MARION	108,729	206,126	0	0	0	0	97,397
METROPOLITAN	0	43,890	0	43,890	0	0	43,890
MID-AMER	85,335	38,280	0	0	0	47,055	0
MID-TEX	10,393	40,497	0	0	0	0	30,104
MOBIL	6,552,119	5,010,325	0	6,042	443,650	1,541,794	0
MOBILE-BAY	0	129,542	0	0	0	0	129,542
MOHAWK	369,125	455,101	173,604	0	64,272	0	85,976
MONOCO	0	4,950	0	4,950	0	0	4,950
MONSANTO	323,552	195,388	0	0	0	128,164	0
MORRISON	17,742	14,526	0	0	0	3,216	0
MOUNTAINEER	8,964	8,464	0	0	0	500	0
MT-AIRY	12,654	128,073	0	0	0	0	115,419
MURPHY	771,612	686,581	0	0	0	85,031	0
N-AMER-PETRO	5,394	133,233	0	0	0	0	127,839
NATL-COOP	245,888	368,163	0	0	0	0	122,275
NAVAJO	390,133	333,838	63,467	0	0	56,295	0
NEVADA	15,130	32,220	0	0	0	0	17,090
NEW-EDGINGTON	621,583	626,539	179,937	0	209,288	0	4,956
NEW-ENGL-PETRO	0	524,617	0	524,617	0	0	524,617
NEWHALL	227,549	221,028	0	0	62,419	6,521	0
NORTHEAST-PETRO	0	7,255	0	7,255	0	0	7,255
NORTHLAND	30,533	21,283	0	0	0	9,250	0
NORTHVILLE	0	24,634	0	24,634	0	0	24,634
OKC	165,340	225,724	0	0	0	0	60,384
OKLA-REF	71,053	146,132	0	0	0	0	75,079
OXNARD	5,611	23,519	0	0	5,032	0	17,908
PEMEX	0	97,786**	0	0	0	0	97,786
PENNZOIL	215,645	300,910	0	0	0	0	85,265
PESTER	154,817	200,761	0	0	0	0	45,944
PHILLIPS	2,463,914	1,556,185	0	0	-1,894	907,729	0
PHILLIPS-PR	0	271,981	0	271,981	0	0	271,981
PIONEER	39,319	58,048	0	0	0	0	18,729
PLACID	204,303	268,621	0	0	0	0	64,318
PLATEAU	135,583	158,835	0	0	0	0	23,252
POWERINE	-66,350	295,969	0	0	-13,681	0	362,319
PR-OLEFINS	0	49,901	0	49,901	0	0	49,901
PRIDE	104,205	154,832	0	0	0	0	50,627

NOTICE OF ENTITLEMENTS FOR DOMESTIC CRUDE OIL

JULY 1978

REPORTING FIRM SHORT NAME	DEEMED OLD OIL ADJUSTED RECEIPTS	********** TOTAL ISSUED	EXCEPTIONS AND APPEALS	ENTITLEMENT POSITION ENTITLEMENTS PRODUCT	CALIFORNIA	REQUIRED TO BUY	********** REQUIRED TO SELL
PRINCETON	1,850	58,312	0	0	0	0	56,462
QUAKER-ST	33,392	209,428	0	0	0	0	176,036
RANCHO-REF	0	11,634	0	0	0	0	11,634
RAYMAL	654	12,819	0	0	0	0	12,165
RICHARDS	190	60,839	0	0	0	0	60,649
RICO	0	10,976	0	10,976	0	0	10,976
ROAD-OIL	0	3,262	0	0	0	0	3,262
ROCK-ISLAND	190,163	312,552	0	0	0	0	122,389
SABER-TEX	18,293	195,912	0	0	0	0	177,619
SABRE-CAL	7,700	76,572	0	0	5,613	0	68,872
SAGE-CREEK	2,254	4,437	0	0	0	0	2,183
SAN-JOAQUIN	446,834	349,828	-13,499	0	190,917	97,006	0
SEMINOLE	1,143	74,922	0	0	0	0	73,779
SENTRY	9,259	120,751	0	0	0	0	111,492
SHELL	9,959,759	6,602,958	0	0	546,919	3,356,801	0
SHEPHERD	13,822	135,428	0	0	0	0	121,606
SIGMOR	-2,650	122,455	0	0	0	0	125,105
SO-HAMPTON	46,375	128,143	0	0	0	0	81,768
SOHIO	1,475,671	2,133,709	0	18,490	0	0	658,038
SOMERSET	20,902	49,711	0	0	0	0	28,809
SOUND	36,184	57,331	0	0	17,618	0	21,147
SOUTHERN-UNION	187,281	223,147	0	0	0	0	35,866
SOUTHLAND	435,267	333,319	129,848	0	0	101,968	0
SOUTHWESTERN	6,832	4,167	0	0	0	2,665	0
SPRAGUE	0	34,627	0	34,627	0	0	34,627
STEUART	0	37,520	0	37,520	0	0	37,520
SUN-TRADING	0	229,507**	0	0	0	0	229,507
SUNLAND	4,937	115,274	0	0	460	0	110,337
SUNOCO	4,094,517	3,092,058	0	0	0	1,002,459	0
SWANN	0	2,744	0	2,744	0	0	2,744
T&S	5,130	81,087	0	0	0	0	75,957
TARRICONE	0	5,484	0	5,484	0	0	5,484
TENNECO	701,658	512,656	0	0	-6,754	189,002	0
TESORO	134,272	409,354	0	0	0	0	275,082
TEXACO	8,374,038	6,235,786	0	239,248	195,489	2,138,252	0
TEXAS-AMERICAN	49,789	103,040	0	0	0	0	53,251
TEXAS-ASPH	12,058	27,135	0	0	0	0	15,077*****
TEXAS-CITY	706,144	357,932	0	0	0	348,212	0
THAGARD	217,496	221,759	28,161	0	68,418	0	4,263
THRIFTWAY	24,956	30,997	0	0	0	0	6,041
THUNDERBIRD	51,948	131,916	0	0	0	0	79,968
TIPPERARY	33,992	73,677	0	0	0	0	39,685
TONKAWA	29,490	53,273	0	0	0	0	23,783
TOSCO	1,725,883	1,951,211	375,203	0	552,616	0	225,328
TOTAL-PETROLEUM	262,867	366,490	0	0	0	0	103,623
UCC-CARIBE	0	160,633	0	160,633	0	0	160,633
UNION-OIL	4,202,785	2,726,423	0	0	228,057	1,476,362	0
UNION-PETRO	0	2,660	0	2,660	0	0	2,660
UNTD-IND	0	1,519	0	0	0	0	1,519
UNTD-REF	71,865	269,332	0	0	0	0	197,467
US&SO-AMER	0	366,603**	0	0	0	0	366,603
US-OIL	12,874	197,557	0	0	4,884	0	184,683
USA-PETROCHEM	21,598	205,650	0	0	6,752	0	184,052
VAL-VERDE	145	2,098	0	0	0	0	1,953
VICKERS	169,357	398,920	0	0	0	0	229,563
VULCAN	0	273,409	0	0	0	0	273,409
WALLER	0	5,508	0	5,508	0	0	5,508
WARRIOR	57,063	41,855	14,909	0	0	15,228	0
WEST-COAST	81,435	146,719	0	0	45,928	0	65,284
WESTERN	73,983	105,321	0	0	0	0	31,338
WINSTON	109,214	170,046	0	0	0	0	60,832
WINEHACK	0	667	0	0	0	0	667
WITCO	83,291	140,557	0	0	29,778	0	57,266
WYATT	0	1,836	0	1,836	0	0	1,836

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WYOMING	41,707	153,224	0	0	0	0	111,517
YETTER	0	618	0	0	0	0	618
YOUNG	47,920	42,372	13,951	0	0	5,548	0
TOTAL	106,114,520	106,114,520	2,998,839	2,486,410	3,702,011	21,441,959	21,441,959

* See discussion in Notice.

** Includes entitlements issued for sales of imported crude oil to the United States Government for storage in the Strategic Petroleum Reserve.

*** Authorization to sell these entitlements is subject to conditions set forth in a DOE Decision and Order issued to Commonwealth Oil and Refining Company on March 20, 1978.

**** This is consistent with the court's order prohibiting any further entitlement purchase requirements by this firm pursuant to the terms of the court's Judgment in Husky Oil Co. v. DOE, et al., Civ. Action No. C77-190-B (D.Wyo., filed March 14, 1978), remanded ___F.2d ___ (No. 10-18 TECA, August 10, 1978).

***** This does not include the purchase obligation stayed by court order in Texas Asphalt & Refinery Co. v. FEA Civ. Action No. 4-75-268 (N.D. Tex., filed October 31, 1975).

[6740-02]

Federal Energy Regulatory Commission

[Docket No. E-7777 (Phase II)]

PACIFIC GAS & ELECTRIC CO. AND SOUTHERN CALIFORNIA EDISON CO.

Extension of Time

SEPTEMBER 11, 1978.

On September 6, 1978, motions were filed by Pacific Gas & Electric Co. and Southern California Edison Co. for additional time to answer the Staff's motion filed August 25, 1978, entitled "Motion for Clarification, or in the Alternative, Request for Investigation and Consolidation." Staff filed an answer to the motions for extension of time stating that it would not oppose a 1-week extension.

Upon consideration, notice is hereby given that an extension of time is granted to and including September 18, 1978, for the filing of answers to Staff's August 25, 1978, motion.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-26375 Filed 9-28-78; 8:45 am]

[4110-03]

ENVIRONMENTAL PROTECTION AGENCY

LABORATORY ANALYTICAL SERVICES

Memorandum of Agreement With the Food and Drug Administration

CROSS REFERENCE: For a document giving notice of a Memorandum of Agreement between the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) setting forth cooperative working arrangements under which FDA will perform water quality related laboratory analytical services for EPA, see FR Doc. 78-27080 appearing elsewhere in this issue of the FEDERAL REGISTER.

[6560-01]

[PF-111; FRL 977-4]

PESTICIDE PROGRAMS

Notice of Filing of Pesticide Petitions

Pursuant to section 408(d)(1) of the Federal Food, Drug, and Cosmetic Act, the Environmental Protection Agency (EPA) gives notice that the following petitions have been submitted to the Agency for consideration.

PP 8F2107. Union Carbide Corp., 1730 Pennsylvania Avenue NW., Washington, D.C. 20006. Proposes that 40 CFR 180.269 be amended by establishing a tolerance for the combined residues of the insecticide/nematocide aldicarb (2-methyl-2-(methylthio) propionaldehyd *O*-(methylcarbamoyl)oxime and its cholinesterase-inhibiting metabolites aldicarb sulfoxide and aldicarb sulfone in or on the raw agricultural commodities grain sorghum at 0.05 part per million (ppm) and fodder at 0.5 ppm. The proposed analytical method for determining residues is by gas chromatography utilizing a Melpar flame-photometric detector. PM12. (202-426-9425)

PP 8F2110. American Hoechst Corp., Agricultural Division, Route 202-206 N., Somerville, N.J. 08876. Proposes that 40 CFR 180 be amended by establishing a tolerance for the combined residues of the herbicide methyl 2-[4-(2,4-dichlorophenoxy) phenoxy] propanoate and its metabolites 2-[4-(2,4-dichlorophenoxy) phenoxy] propanoic acid and 2-4-(2,4-dichloro-5-hydroxyphenoxy) phenoxy propanoic acid in or on the raw agricultural commodity soybean seed at 0.10 ppm. The proposed analytical method for determining residues is by gas liquid chromatographic procedure using an electron capture device. PM23. (202-755-1397)

PP 8F2117. E.I. DuPont De Nemours & Co., Wilmington, Del. 19898. Proposes that 40 CFR 180.303 be amended by establishing a tolerance for the residues of the insecticide oxamyl (methyl *N'*, *N'*-dimethyl-*N*-[(methylcarbamoyl)oxy]-1-thiooxamimidate) in or on the raw agricultural commodities corn grain (field, sweet, and popcorn), corn fodder, and forage at 0.1 ppm. Proposed analytical method for determining residues is by gas chromatography with sulfur sensitive flame-photometric detector. PM12.

Interested persons are invited to submit written comments on these petitions to the Federal Register Section, Program Support Division (TS-757), Office of Pesticide Programs, EPA, Room 401, East Tower, 401 M Street SW., Washington, D.C. 20460. Inquiries concerning these petitions may be directed to the designated product manager (PM), Registration Division (TS-767), Office of Pesticide Programs, at the above address, or by telephone at the numbers cited. Written comments should bear a notation indicating the petition number to which the comments pertain. Comments may be made at any time while a petition is pending before the Agency. All written comments filed pursuant to this notice will be available for public inspection in the office of the Federal Register Section from 8:30 a.m. to 4 p.m., Monday through Friday.

Dated: September 22, 1978.

DOUGLAS D. CAMPT,
Acting Director,
Registration Division.

[FR Doc. 78-27400 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 977-5; OPP-180234]

DEPARTMENT OF THE INTERIOR

Issuance of a Specific Exemption To Use Sodium Cyanide in M-44 Device To Control Predation of Coyotes on Whooping Cranes

The Environmental Protection Agency (EPA) has granted a specific exemption to the Fish and Wildlife Service, U.S. Department of the Interior (hereafter referred to as "USDI") to use sodium cyanide-loaded M-44 devices in order to control coyotes which are threatening an endangered species, the whooping crane, in the Grays Lake National Wildlife Refuge in Idaho. This exemption was granted in accordance with, and is subject to, the provisions of 40 CFR Part 166, which prescribes requirements for exemption of Federal and State agencies for use of pesticides under emergency conditions.

This notice contains a summary of certain information required by regulation to be included in the notice. For more detailed information, interested parties are referred to the application on file with the Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Room E-315, Washington, D.C. 20460.

According to the USDI, a recovery project for restoring whooping crane (*Grus americana*) populations began in 1975 at the Grays Lake National Wildlife Refuge in Idaho. The success of this restoration project is being threatened by coyotes (*Cranis laetrans*) which prey upon eggs and hatchlings of the whooping cranes. In 1977, eight eggs and three whooping crane chicks were taken by one pair of coyotes and pups denning in the area. The USDI stated that a number of methods for coyote control have been tried (aerial hunting, calling, shooting, and trapping), but these methods have not provided adequate control of this predator. Heavy vegetative growth prevents aerial hunting from being effective at this time of the year. This species will continue to remain endangered unless additional flocks can become established.

A 1972 Presidential order (Executive Order 11643) prohibits the use of chemical toxicants, such as the sodium cyanide-loaded M-44 device, on Federal lands except in emergency conditions. One of these conditions is for the protection of one or more wildlife species threatened with extinction or likely within the foreseeable future to become so threatened. The U.S. Fish and Wildlife Service has the responsibility for the restoration of endangered species under the Endangered

Species Act of 1973. Since the whooping crane is an endangered species, there would be compliance with the Presidential order. The USDI has conformed to the provision in the Presidential order which requires that the agency involved in the use of chemical toxicants confer with the Secretaries of Agriculture, Health, Education, and Welfare, the Interior, the Administrator, EPA, before such chemical toxicants are applied. In addition, the EPA has issued a registration to the USDI for the use of the M-44 device to control coyotes, foxes, and feral dogs which prey upon livestock. Thus, issuance of the specific exemption is justified from the standpoint that the M-44 device is being employed under emergency conditions and by a qualified agency experienced in the use of this device for predator control.

Adverse effects resulting from the use of the sodium cyanide-loaded M-44 device in the Grays Lake National Wildlife Refuge area is unlikely. This refuge consists of approximately 15,000 acres of marsh and upland, and is primarily a waterfowl refuge area. The M-44 device will be placed on only 500 acres in this refuge and only for a limited period of time (120 days). Coyote control is considered necessary particularly because of the high avian population; thus, the use of the M-44 device here would also fit into the overall wildlife management program. Since refuge personnel and one grazer are the only person permitted on the site, the chances of humans accidentally discharging the M-44 devices are remote.

After reviewing the application and other available information, EPA has determined that (a) an emergency situation involving an endangered species has been found to exist; (b) there are no alternative means of control, taking into account the efficacy and hazard; (c) significant environmental problems may result if the coyotes are not removed from the Grays Lake National Wildlife Refuge; and (d) the time available for action to mitigate the problems posed is insufficient for a pesticide to be registered for this use. Accordingly, the USDI has been granted a specific exemption to use the pesticide noted above until October 31, 1978, to the extent and in the manner set forth in the application. The specific exemption is also subject to the following conditions:

1. A maximum of 75 M-44 devices containing a total of 33.75 grams of sodium cyanide is authorized;

2. The M-44 devices are to be placed on 500 acres of land at Grays Lake National Wildlife Refuge in Idaho;

3. Only trained Fish and Wildlife personnel shall hand place the M-44 devices;

4. All unused sodium cyanide capsules shall be recovered at the end of the season;

5. All precautions shall be taken to avoid or minimize hazards to nontarget species that may result from this program;

6. All label precautions including the posting of warning signs must be adhered to;

7. Any adverse effects resulting from the use of M-44 devices in connection with this specific exemption must be reported to the EPA immediately; and

8. A report summarizing the results of this program must be submitted to the EPA by December 31, 1978.

STATUTORY AUTHORITY: Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.).

Dated: September 22, 1978.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 78-27399 Filed 9-28-78; 8:45 am]

[6560-01]

[FRL 977-6; OPP-180233]

LOUISIANA DEPARTMENT OF AGRICULTURE

Issuance of a Specific Exemption To Use 2,4-D To Control Sesbania on Soybeans

The Environmental Protection Agency (EPA) has granted a specific exemption to the Louisiana Department of Agriculture (hereafter referred to as the "Applicant") to use a dimethylamine salt of 2,4-D for the control of sesbania on 40,000 acres of soybean plants in 48 parishes (counties) in Louisiana. This exemption was granted in accordance with, and is subject to, the provisions of 40 CFR Part 166, which prescribes requirements for exemption of Federal and State agencies for use of pesticides under emergency conditions.

This notice contains a summary of certain information required by regulation to be included in the notice. For more detailed information, interested parties are referred to the application on file with the Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M Street SW., Room E-315, Washington, D.C. 20460.

According to the Applicant, the weed sesbania, primarily hemp sesbania (*Sesbania exaltata*), may significantly reduce the yield of the soybean crop on 40,000 acres in Louisiana. In most previous years, satisfactory weed control has been obtained by using preplant incorporated, preemergence, and overtop herbicides. However, the Applicant stated that when high rainfall occurs, which causes dissipation of herbicides and greater weed germination, sesbania emerges through the soybean canopy and, without additional control measures, may reduce yield 50 percent or more. Yield reduction occurs as a result of the weeds taking fertilizer and water away from the soybeans, from shading resulting in the lack of adequate amounts of sunlight and by excessive harvest losses. The Applicant stated that the occurrence of this pest is particularly severe this year in portions of the rice and sugarcane producing areas of south Louisiana. The overtop sprays 2,4-DB (Butoxone and Butyrac) and Basagran are being used to control sesbania prior to bloom stage of soybean plants; however, research conducted by Louisiana State University indicates that in Louisiana these products will not control sesbania that has emerged through the soybean canopy.

The Applicant will use a single application of 2,4-D by air as an overtop foliage spray on 40,000 acres of soybeans in the 48 parishes affected. The herbicide will be applied at the rate of 4 to 8 ounces of a 4-pound-per-gallon active ingredient, amine 2,4-D, per acre. The herbicide will be applied in 3 to 5 gallons of water per acre. This is equivalent to one-eighth to one-quarter pound of 2,4-D acid equivalent per acre applied as the amine salt. In order to obtain maximum results and prevent yield reduction and excess residues in harvested beans, two conditions are necessary: The sesbania canopy cover must exceed 75 percent, and the stage of maturity of the bean must be after pod-set and before beans can be felt in the pod. Best control will be obtained if the weeds are sprayed when in full bloom.

All aerial applications will be made by certified applicators who are licensed by the Applicant. To prevent damage to other susceptible crops in the area of application, special permission will be obtained from the commissioner of the Louisiana Department of Agriculture for the use of 2,4-D, except in the southwestern part of the State where cotton is not grown.

2,4-D is a widely used herbicide and tolerances have been established on foods that make up approximately 80 percent of the total average human diet. EPA has determined that soybeans with residues of 2,4-D ranging from 0.2 part per million (ppm) to a maximum of 0.75 ppm pose a negligible hazard to human health. EPA has also considered the potential for residues from nitrosamine contamination of the chemical and has calculated that such residues would be less than 1 part per billion (ppb), which level should also not pose undue hazard to the environment.

It appears that income derived from soybeans is very important to Louisiana farmers. Because of the low prices farmers are receiving for rice, many of

them are more dependent than usual on income from soybeans. According to the Applicant unless 2,4-D can be applied, the average yield on the 40,000 acres of soybean plants infested with sesbania may be reduced by approximately 10 bushels per acre. At $6 per bushel, this represents a dollar loss of $2,400,000.

After reviewing the application and other available information, EPA has determined that (a) a pest outbreak of sesbania has occurred; (b) there is no pesticide presently registered and available for use to control sesbania in soybean fields in Louisiana; (c) there are no alternative means of contol, taking into account the efficacy and hazard; (d) significant economic problems may result if the sesbania is not controlled; and (e) the time available for action to mitigate the problems posed is insufficient for a pesticide to be registered for the use. Accordingly, the Applicant has been granted a specific exemption to use the pesticide noted above until October 15, 1978, to the extent and in the manner set forth in the application. The specific exemption is also subject to the following conditions:

1. A dimethylamine salt of 2,4-D will be applied at the rate of from one-eighth to one-quarter pound 2,4-D acid equivalent per acre;

2. An overtop foliage, aerial application will be limited to 40,000 acres in the following 48 parishes: Acadia, Allen, Ascension, Assumption, Avoyelles, Beauregard, Calcasieu, Caldwell, Cameron, Catahoula, Concordia, East Baton Rouge, East Carroll, East Feliciana, Evangeline, Franklin, Grant, Iberia, Iberville, Jefferson Davis, Lafourche, Lafayette, Livingston, Madison, Morehouse, Natchitoches, Quachita, Pointe Coupee, Rapides, Red River, Richland, Sebine, St. Charles, St. Helena, St. James, St. John the Baptist, St. Landry, St. Martin, St. Tammany, Tangipahoa, Tensas, Terrebonne, Vernon, Vermilion, Washington, West Carroll, West Baton Rouge, and West Feliciana;

3. The total quantity of 2,4-D to be applied will not exceed 10,000 pounds of active ingredient;

4. 2,4-D is to be applied only when the following conditions exist: (a) The sesbania canopy must exceed 75 percent; and (b) the stage of maturity of the bean must be after pod set and before beans can be felt in the pods of the four uppermost nodes;

5. Aerial applications will be made by certified applicators licensed by the Louisiana Department of Agriculture;

6. Special permission will be obtained from the commissioner of the Louisiana Department of Agriculture for all applications of 2,4-D in designated restricted areas;

7. Residue levels in soybeans not exceeding 0.75 ppm of 2,4-D have been deemed adequate to protect the public health. The Food and Drug Administration, U.S. Department of Health, Education, and Welfare, has been advised of this action;

8. A 30-day interval for grazing livestock on treated soybean fields will be observed;

9. The Applicant shall continue to cooperate with the IR-4 program in order that a permanent tolerance for 2,4-D on soybeans may be obtained;

10. Precautions must be taken to avoid or minimize spray drift to nontarget areas;

11. Applications will not be made to any body of water;

12. The EPA shall be immediately informed of any adverse effects resulting from the use of 2,4-D in connection with this exemption; and

13. A report which summarizes the benefits obtained from the use of 2,4-D under this specific exemption must be submitted to the EPA by March 31, 1979.

STATUTORY AUTHORITY: Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (86 Stat. 973; 89 Stat. 751; 7 U.S.C. 136(a) et seq.).

Dated: September 22, 1978.

EDWIN L. JOHNSON,
Deputy Assistant Administrator for Pesticide Programs.

[FR Doc. 78-27398 Filed 9-28-78; 8:45]

[1505-01]

FEDERAL TRADE COMMISSION

PRIVACY ACT ISSUANCES

Incorporation by Reference

Correction

In FR Doc. 78-24579 appearing on page 40110 in the issue of Friday, September 8, 1978, on page 40113 in the 2nd column under "FTC-26", the addresses for the Cleveland and Dallas offices should read:

* * * * *

Cleveland Regional Office
Suite 500, Mall Building
118 Saint Clair Avenue
Cleveland, Ohio 44114

Dallas Regional Office
2001 Bryan Tower, Suite 2665
Dallas, Tex. 75201

* * * * *

On page 40116 in the right-hand column, the 2nd line should read, "Suite 500, Mall Building".

In the same column, the last line should read, "* * * exempt from mandatory disclosure under 5 U.S.C. Sec 552a (k)(2).".

[1610-01]

GENERAL ACCOUNTING OFFICE

REGULATORY REPORTS REVIEW

Receipt of Report Proposal

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review staff, GAO, on September 25, 1978. See 44 U.S.C. 3512 (c) and (d). The purpose of publishing this notice in the FEDERAL REGISTER is to inform the public of such receipt.

The notice includes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed ICC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before October 17, 1978, and should be addressed to Mr. John M. Lovelady, Assistant Director, Regulatory Reports Review, U.S. General Accounting Office, room 5106, 441 G Street NW., Washington, D.C. 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review staff, 202-275-3532.

INTERSTATE COMMERCE COMMISSION

The ICC requests an extension without change clearance of Form OS-C, Quarterly Report of Operating Statistics, Motive Power and Car Equipment, required to be filed by some 43 class I railroads pursuant to section 20 of the Interstate Commerce Act. Data collected by form OS-C are used for economic regulatory purposes. ICC states that no change is made in the data requirements and that the reports are mandatory and available for use by the public. ICC estimates the reporting burden for carriers averages 46 hours for line-haul and 14 hours for switching and terminal companies per report.

NORMAN F. HEYL,
Regulatory Reports Review Officer.

[FR Doc. 78-27458 Filed 9-28-78; 8:45 am]

[6820-22]

GENERAL SERVICES ADMINISTRATION

REGIONAL PUBLIC ADVISORY PANEL ON ARCHITECTURAL AND ENGINEERING SERVICES

Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting on architectural and engineering services, region 9, October 13 from 9 a.m. through 4:15 p.m., Conference Room, Construction Management Division, 31st Floor, Tishman Building, 525 Market Street, San Francisco, Calif. The meeting anticipates the review of the conceptual designs for an addition to the NARS Record Center, San Bruno, Calif.; a Federal correctional institution, Los Angeles area, California; and a Federal parking facility, Los Angeles, Calif. The meeting will be open to the public.

ROSS A. BIATEK,
Acting Regional Administrator.

[FR Doc. 78-27485 Filed 9-28-78; 8:45 am]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 78N-0270]

GARDEN STATE BLOOD BANK, INC.

Revocation of U.S. License No. 320

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs revokes the establishment and product licenses of Garden State Blood Bank, Inc. (U.S. license No. 320) to manufacture source plasma (human) and whole blood (human) because of significant deviations from the biologics regulations.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael L. Hooton, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: The Commissioner is revoking the establishment and product licenses, issued to Garden State Blood Bank, Inc., 127 Washington Street, Newark N.J. 07102, (U.S. license No. 320) to manufacture source plasma (human) and whole blood (human).

An inspection of Garden State Blood Bank, Inc., on May 17, 18, and 22, 1978, by investigators of the Food and Drug Administration (FDA) revealed numerous deviations from the requirements of part 600 (21 CFR Part 600), including the interstate shipment of whole blood (human) without the firm having in its possession the proper test records for the presence of hepatitis B surface antigen (see § 610.40(b)(3) (21 CFR 610.40(b)(3))). This significant deviation was one of many items cited previously in an FDA inspection of the firm in November 1977 that resulted in a suspension of its operations from November 11, 1977, through March 13, 1978.

As a result of the most recent inspection and under § 601.6(a) (21 CFR 601.6(a)), the agency notified Garden State Blood Bank, Inc., in a letter dated July 18, 1978, that the agency had again suspended the firm's operations and that the agency intended to revoke U.S. license No. 320 and issue an opportunity for hearing.

In response to the July 18, 1978, letter issued to Garden State Blood Bank, Inc., the firm has requested that its establishment and product licenses be revoked and has waived the opportunity for a hearing under § 601.5(a) (21 CFR 601.5(a)). The Commissioner is granting the request. Accordingly, under § 12.38 (21 CFR 12.38), section 351 of the Public Health Service Act (42 U.S.C. 262), and the authority delegated to the Commissioner (21 CFR 5.1), U.S. license No. 320 issued to Garden State Blood Bank, Inc., and the firm's product licenses for the manufacture of source plasma (human) and whole blood (human), are hereby revoked as of the date of signature. This notice of revocation is published under § 601.8 (21 CFR 601.8).

Dated: September 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27240 Filed 9-28-78; 8:45 am]

[4110-03]

MEDICAL DEVICE CLASSIFICATION PANELS

Request for Nominations for Nonvoting Representatives of Industry Interests on Public Advisory Committees; Extension of Due Date

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice extends the due date for receipt of nominations of industry representatives on public advisory committees.

DATE: Nominations should be received by Novenber 28, 1978, for vacancies indicated in the previous notice.

ADDRESS: All nominations for industry representatives must be submitted in writing to: Kay A. Levin, Bureau of Medical Devices (HFK-50), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, Md. 20910.

FOR FURTHER INFORMATION CONTACT:

Robert S. Kennedy, Bureau of Medical Devices (HFK-401), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, Md. 20910, 301-427-7900.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of June 30, 1978 (43 FR 28554), the Food and Drug Administration published a notice soliciting nominations for nonvoting representatives of consumer and industry interests and established a due date of July 31, 1978, for receipt of nominations. The agency has a special interest in assuring that women and minority groups are adequately represented on advisory committees and therefore extends particular encouragement to nominations for appropriately qualified women and minority candidates. This notice is issued under the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 779-776 (5 U.S.C. App. I)) and 21 CFR Part 14, relating to advisory committees.

Dated: September 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27082 Filed 9-28-78; 8:45 am]

[4110-03]

ONCOLOGIC DRUGS ADVISORY COMMITTEE

Re-Establishment

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), the Food and Drug Administration announces the re-establishment of the Oncologic Drugs Advisory Committee by the Secretary, Department of Health, Education, and Welfare.

DATE: Authority for this Committee will expire on September 1, 1980, unless the Secretary formally determines that continuance is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Officer (HFA-27), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

Dated: September 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27083 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket No. 78N-0271]

PIONEER BLOOD SERVICE, INC.

Revocation of U.S. License No. 278

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs revokes the establishment and product licenses of Pioneer Blood Service, Inc., at the Raleigh, N.C. location (U.S. license No. 278) to manufacture source plasma (human), whole blood (human), red blood cells (human), and single donor plasma (human) at that location because of significant deviations from the biologics regulations.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Michael L. Hooton, Bureau of Biologics (HFB-620), Food Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, Md. 20014, 301-443-1306.

SUPPLEMENTARY INFORMATION: The Commissioner is revoking the establishment and product licenses for the Raleigh, N.C., location (U.S. license No. 278) of Pioneer Blood Service, Inc., 30 Sherman Avenue, New York, N.Y. 10040, for the manufacture of source plasma (human), whole blood (human), red blood cells (human), and single donor plasma (human).

An inspection of Pioneer Blood Service, Inc., 108 South Wilmington Street, Raleigh, N.C. 27602, on June 20 through 22, 1978, by investigators of the Food and Drug Administration (FDA) revealed numerous deviations from the requirements of part 600 (21 CFR Part 600), including the collection of more than the maximum permissible amount of whole blood from donors during a 7-day period (see § 640.65(b)(5) (21 CFR 640.65(b)(5))). This significant deviation was one of many items cited previously in an FDA inspection of the location in 1975 that resulted in a suspension of the Raleigh location from November 12 through December 9, 1975.

As a result of this most recent inspection, the establishment and product licenses issued for that location were suspended on June 28, 1978, under § 601.6(a) (21 CFR 601.6(a)). On July 10, 1978, the agency sent a letter to Pioneer Blood Service, Inc., confirming the suspension and setting forth the grounds for the suspension and revocation.

In response to the July 10, 1978, letter issued to Pioneer Blood Service, Inc., the firm has requested that its licenses for the Raleigh location and the products manufactured at that location be revoked and has waived the opportunity for a hearing under § 601.5(a) (21 CFR 601.5(a)). The Commissioner is granting the request. Accordingly, under § 12.38 (21 CFR 12.38), section 351 of the Public Health Service Act (42 U.S.C. 262), and the authority delegated to the Commissioner (21 CFR 5.1), the Raleigh, N.C., location of Pioneer Blood Service, Inc., and the product licenses for the Raleigh location under U.S. license No. 278, are hereby revoked as of the date of signature. This notice of revocation is published under § 601.8 (21 CFR 601.8).

Dated: September 21, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27239 Filed 9-28-78; 8:45 am]

[4110-03]

[FDA 225-78-4005]

WATER QUALITY ANALYSIS

Memorandum of Agreement With the Environmental Protection Agency

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has executed a memorandum of agreement with the Environmental Protection Agency (EPA). The purpose of the agreement is to set forth cooperative working arrangements under which FDA will perform water quality related laboratory analytical services for EPA.

DATE: The agreement became effective July 1, 1978.

FOR FURTHER INFORMATION CONTACT:

Gary Dykstra, Compliance Coordination and Policy Staff (HFC-13), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-3470.

SUPPLEMENTARY INFORMATION: Pursuant to the notice published in the FEDERAL REGISTER of October 3, 1974 (39 FR 35697) stating that future memoranda of understanding and agreements between FDA and others would be published in the FEDERAL REGISTER, the Commissioner of Food and Drugs is issuing the following memorandum of agreement:

INTERAGENCY AGREEMENT BETWEEN U.S. FOOD AND DRUG ADMINISTRATION AND THE U.S. ENVIRONMENTAL PROTECTION AGENCY

Purpose: The U.S. Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minn., will perform certain laboratory functions for the U.S. Environmental Protection Agency, 7401 Lyndale Avenue South, Minneapolis, Minn. Such performance is in accord with the August 2, 1977 announcement by administrators of these agencies that they would explore "* * * whether laboratory as well as other facilities could be shared".

Scope of work: By virtue of this agreement, the U.S. Food and Drug Administration (FDA) will perform water quality related laboratory analytical services for the U.S. Environmental Protection Agency (EPA). Such analyses would include, but not be limited to, the following chemistry parameters: 5-day biochemical oxygen demand; suspended, dissolved, and total solids; turbidity; specific conductance; pH; hexavalent chromium; sulfide; oil and grease; phenols; cyanide; and selected organic compounds. Microbiological analysis of water samples for total coliform, fecal coliform and fecal streptococcus would also be performed as requested in the attached letter (Attachment 1).[1] These analytical services will be supplied based on routine quarterly requests as well as special requests for analyses. In the case of special requests for analysis, advance mutual agreement between EPA and the appropriate FDA laboratory director is required with respect to sample delivery date, analysis needed and time necessary for analysis. The quality of the analytical data generated will be documented by the FDA and reviewed periodically by the EPA.

Provisions: In fulfilling its responsibilities with respect to this agreement, the EPA will:

1. Provide Analytical Request and Reporting Forms (Attachment 2),[1] documenting the projected dates of sample delivery and the analyses to be performed, to FDA at least 1 week prior to the beginning of each fiscal year quarter. Notification of changes will be given to FDA at least 1 week prior to the projected sampling date, except when a rare emergency situation occurs allowing for only 24 hour notice.

2. Collect and deliver the samples to be analyzed to the FDA. EPA chain of custody procedures will be followed through the delivery of samples to the FDA analyst (Attachment 3).[1] FDA custody procedures will apply for all samples after they are received by the FDA analyst.

3. Label all samples clearly with labels (see examples—Attachment 6) [1] and with appropriate sample numbers which should follow the samples on all chain of custody forms, analytical work and reporting forms, etc.

4. Provide all sample containers, both reusable and discardable. FDA will clean and return reusable sample containers to EPA.

5. On a quarterly basis, notify the FDA when analyzed samples may be discarded.

6. Provide FDA with updates to the EPA methods manual, copies of the EPA Analyt-

[1] Filed as part of the original document.

ical Quality Control Newsletter and reference performance samples as requested.

In fulfilling its responsibilities with respect to this agreement, the FDA will:

1. Advise EPA if planned sample collection dates are unsatisfactory.

2. Receive EPA samples as scheduled and log them into the sample accountability security system using FDA Form FD-421 (Attachment 5).' These forms will be kept by FDA for two (2) years and then be transmitted to EPA for storage or disposal.

3. Maintain accountability/custody of the samples through laboratory analytical processing and storage.

4. Perform all analyses according to EPA approved methods of analysis as required by 40 CFR [Part] 136, FEDERAL REGISTER of December 1, 1978 [sic; read "1976"] and corrected on July 20, 1977).

5. Submit reports of results of sample analysis to EPA on Form FD-431 (Attachament 7)' or 431A within 10 working days of receipt of samples.

6. Participate in an EPA quality assurance program as specified by the Region V, Quality Assurance Office. The program will include the analysis of reference samples, split samples, and duplicate samples with sufficient data evaluation such that a summary report documenting the precision of reported data can be prepared and submitted periodically to the Quality Assurance Office, at the request of the EPA.

7. Provide testimony in Federal litigation involving EPA samples. This testimony should support both the chain of custody and the application of EPA analytical methods. EPA will defend the methods.

Duration of agreement: This agreement will commence July 1, 1978, and will continue through fiscal year 1979. Extension of this agreement beyond fiscal year 1979 is anticipated with the terms reviewed and revised as necessary. Conversely, this agreement may be terminated at any time via a 30-day written notice submitted by either party to the other.

Reports: Analytical reports and quality assurance reports will be submitted by the FDA to the EPA on the frequency described in Provisions above. Original copies of all analytical reports should be sent to:

U.S. Environmental Protection Agency, Region V, Western District Office, 7401 Lyndale Avenue South, Minneapolis, Minn. 55423.

Single copies of all quality assurance reports should be sent to the Western District Office as well as to:

Quality Assurance Office, U.S. Environmental Protection Agency, Region V, 536 South Clark Street, Chicago, Ill. 60605, 312-354-9317 (FTS).

Principle Agency Contacts: Mr. James I. Roberts, Laboratory Director, U.S. Department of Health, Education, and Welfare, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, Minn. 55401, 612-725-2121 (FTS) and Mr. John R. Helvig, U.S. Environmental Protection Agency, Region V, Western District Office, 7401 Lyndale Avenue South, Minneapolis, Minn. 55423, 612-725-3272 (FTS).

Resource Projections: A total of 1,660 hours of analytical and administrative work will be allocated by the FDA. There will be no exchange of funds between the agencies. Total anticipated manpower expenditure for services provided by the FDA will be as follows:

	Cost in hours/sample	
	First sample	*Each additional
Chemistry:		
Five-day biochemical oxygen demand; total, dissolved and suspended solids; pH, conductivity; and turbidity	11.5	4.1
Oil and grease	2.0	0.5
Phenols	3.0	0.5
Cyanide	3.0	1.0
Hexavalent chromium	3.0	1.0
Sulfide	2.0	0.5
Alkalinity	2.0	0.5
Microbiology:		
Fecal coliform	2.0	0.33
Total coliform	2.0	0.33
Fecal streptococcus	2.0	0.33

*On any given *day* when samples are scheduled to arrive in the laboratory.

Other analyses such as metals, organic scans or specific organic compound determinations may be performed by FDA at the request of EPA.

AUTHORITY: The statutory authority under which this agreement is entered into is: The Economy Act of 1932, as amended (31 U.S.C. 686).

Dated: June 23, 1978.

VALDAS V. ADAMKUS,
Acting Regional Administrator,
Environmental Protection Agency.

Dated: June 28, 1978.

LLOYD R. CLAIBORNE,
Regional Director,
Food and Drug Administration.

Effective date. This Memorandum of Agreement became effective July 1, 1978.

Dated: September 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner,
Regulatory Affairs.

[FR Doc. 78-27080 Filed 9-28-78; 8:45 am]

[4110-03]

[Docket No. 78P-0287]

WIEN LABORATORIES

Request for Data and Information on Petition for Reclassification

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) invites interested persons to submit information, data, and views on a petition filed for reclassification of a medical device from class III (premarket approval) into class II (performance standards). The petition was submitted by Wien Laboratories, Inc., Succasunna, N.J. 07876, for a device for the quantitative determination of antidepressant drugs. Material submitted will be forwarded to members of the Clinical Toxicology Device Classification Panel who will make a recommendation on the petition to the FDA.

DATE: Information, data, and views should be submitted by October 30, 1978.

ADDRESSES: Copies of the petition are available at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 2-0857. Information, data, and views should be submitted (preferably five copies) to S. K. Vadlamudi, Executive Secretary, Clinical Toxicology Device Classification Panel (address below).

FOR FURTHER INFORMATION CONTACT:

S. K. Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7234.

SUPPLEMENTARY INFORMATION: On July 5, 1978, Wien Laboratories, Inc., Succassunna, N.J. 07876, submitted under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)), a premarket notification of its intent to market a device for the quantitative determination of antidepressant drugs. The manufacturer calls the device "Tri-Cy Test Set." The product utilizes radiolabeled imipramine and charcoal separation for the quantitative determination of imipramine, desipramine, amitriptyline, nortriptyline, protriptyline, or doxepin in serum.

The Commissioner of Food and Drugs has determine that the device is not substantially equivalent to any device that was in commercial distribution before May 28, 1976; nor is the device substantially equivalent to a device that has been placed in commercial distribution since that date and subsequently reclassified. Therefore, the device is classified automatically into class III under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). On August 14, 1978, Wien Laboratories submitted, under section 513(f)(2) of the act, a reclassification petition for the device.

Under section 515(a)(2) of the act (21 U.S.C. 360e(a)(2)), before a device that is in class III under section 513(f)(1) of the act can be marketed, it must either be reclassified under section 513(f)(2) of the act or have an approval of an application for premarket approval under section 515 of the act, unless there is in effect for the device an investigational device exemption

under section 520(g) of the act (21 U.S.C. 360j(g)).

The agency reviewed the petition and determined that it is not deficient.

Section 513(f) of the act requires the Commissioner to submit the petition to a device classification panel for recommendation concerning classification. The Panel is required to make its recommendation to the Commissioner within 90 days after the petition is referred to the Panel. Ordinarily, the petition would be discussed in an open panel meeting before the Panel makes its recommendation. However, a meeting of the Clinical Toxicology Device Classification Panel could not be scheduled so as to enable the Panel to make its recommendation within the required 90-day period. Therefore, this petition has been mailed to the voting members of the Panel for their review and recommendation to FDA. The Panel will make its recommendation to FDA by mail.

Section 513(f) of the act also requires the Commissioner to provide an opportunity for interested persons to provide information, data, and views to the Panel before it makes its recommendation. Information, data, and views will be mailed to the Panel members for their consideration before they make their recommendation. Then each voting member will send the Executive Secretary of the Panel a completed supplemental data sheet and a completed classification questionnaire applicable to the device for which a recommendation is sought. The Panel recommendation will be published in the FEDERAL REGISTER. A period for public comment will follow, and then the Commissioner will issue a final order approving or denying the petition no more than 210 days after the submission of an adequate petition.

Dated: September 20, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 78-27081 Filed 9-28-78 8:45 am]

[4110-08]

National Institutes of Health

ETHICS ADVISORY BOARD

Meeting and Public Hearing

Notice is hereby given that the Ethics Advisory Board will hold a meeting and public hearing on the subject of the Department's support of research involving human in vitro fertilization of October 13 and 14, 1978, John F. Kennedy Building, Government Center, Boston, Mass. 02203, in conference room 2003A. The meeting and public hearing will convene at 9 a.m. on both days and will be open to the public, subject to the limitation of available space.

Any person wishing to speak at the hearing must receive prior approval from the Board. Requests must include a brief summary of the presentation, which should be limited to 5 minutes. In order to be considered for approval, requests to speak at the meeting must be received no later than October 6, 1978, at the following address: Ethics Advisory Board, Westwood Building, Room 125, 5333 Westbard Avenue, Bethesda, Md. 20016, telephone number 301-496-7776. Written materials of any length may be submitted at any time.

The agenda for the meeting will include presentation of expert witnesses, public testimony and deliberations by the Board on whether the Department of Health, Education, and Welfare should support research involving human in vitro fertilization. In addition, the Board will consider an application for DHEW support of research involving fetal fetoscopy. Future topics for review and study by the Board may also be discussed.

Requests for information should be directed to Dr. Charles R. McCarthy, Westwood Building, Room 125, 5333 Westbard Avenue, Bethesda, Md. 20016, 301-496-7776.

Dated: September 22, 1978.

SUZANNE L. FREMEAU,
Committee Management Officer, National Institutes of Health

[FR Doc. 78-27644 Filed 9-28-78; 8:45 am]

[4110-08]

REPORT ON BIOASSAY OF DICOFOL FOR POSSIBLE CARCINOGENICITY

Availability

Dicofol (CAS 115-32-2) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary. A bioassay of technical-grade dicofol for possible carcinogenicity was conducted using Osborne-Mendel rats and B6C3F1 mice. Applications of the chemical include use as a pesticide. Dicofol was administered in the feed, at either of two concentrations, to groups of 50 males and 50 females of each species.

Under the conditions of this bioassay, technical-grade dicofol was carcinogenic in male B6C3F1 mice, causing hepatocellular carcinomas. No evidence for carcinogenicity was obtained for this compound in Osborne-Mendel rats of either sex or in female B6C3F1 mice.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Md. 20014.

(Catalog of Federal Domestic Assistance Program No. 13.393, Cancer Cause and Prevention Research.)

Dated: August 25, 1978.

LEON M. SCHWARTZ,
Acting Director, National Institutes of Health.

[FR Doc. 78-27260 Filed 9-28-78 8:45 am]

[4110-08]

REPORT ON BIOASSAY OF TRICHLOROFLUOROMETHANE FOR POSSIBLE CARCINOGENICITY

Availability

Trichlorofluoromethane (CAS 75-69-4) has been tested for cancer-causing activity with rats and mice in the Bioassay Program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary. The bioassay of technical-grade trichlorofluoromethane for possible carcinogenicity was conducted using Osborne-Mendel rats and B6C3F1 mice. Applications of the chemical include use as an aerosol propellant and as a refrigerant. Trichlorofluoromethane in corn oil was administered by gavage, at either of two dosages, to groups of 50 male and 50 female animals of each species.

The results of the bioassay of trichlorofluoromethane in Osborne-Mendel rats for possible carcinogenicity are not conclusive because inadequate numbers of rats survived long enough to be at risk from late-developing tumors. Under the conditions of this bioassay, trichlorofluoromethane was not carcinogenic to male or female B6C3F1 mice.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Md. 20014.

(Catalog of Federal Domestic Assistance Program No. 13.393, Cancer Cause and Prevention Research.)

Dated: August 25, 1978.

LEON M. SCHWARTZ,
Acting Director, National Institutes of Health.

[FR Doc. 78-27259 Filed 9-28-78 8:45 am]

[4110-08]

REPORT ON BIOASSAY OF M-CRESIDINE FOR POSSIBLE CARCINOGENICITY

Availability

m-Cresidine (CAS 102-50-1) has been tested for cancer-causing activity with rats and mice in the bioassay program, Division of Cancer Cause and Prevention, National Cancer Institute. A report is available to the public.

Summary. A bioassay of technical-grade m-cresidine for possible carcinogenicity was conducted using Fischer 344 rats and B6C3F1 mice. Applications of the chemical include use as an intermediate in the manufacture of dyes. m-Cresidine in corn oil was administered by gavage 5 days a week at either of two dosages, to groups of 50 male and 49 or 50 female animals of each species.

Under the conditions of this bioassay, m-cresidine was carcinogenic to Fischer 344 rats, causing papillary transitional-cell carcinomas of the urinary bladder in both sexes. No convincing evidence was provided for carcinogenicity in female B6C3F1 mice. Poor survival of male B6C3F1 mice receiving m-cresidine precluded evaluation of the possible carcinogenicity of the compound in these animals.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, National Institutes of Health, Bethesda, Md. 20014.

(Catalog of Federal Domestic Assistance Program No. 13.393, Cancer Cause and Prevention Research.)

Dated: August 25, 1978.

LEON M. SCHWARTZ,
Acting Director,
National Institutes of Health.

[FR Doc. 78-27261 Filed 9-28-78; 8:45 am]

[4110-35]

Office of the Secretary

MEDICARE PROGRAM

Inpatient Hospital Deductible for 1979

Under the authority in section 1813(b)(2) of the Social Security Act (42 U.S.C. 1395e(b)(2)), I have determined and hereby announce that the medicare inpatient hospital deductible for 1979 shall be $160.

Section 1813 of the Social Security Act provides for an inpatient hospital deductible and certain coinsurance amounts to be deducted from the amount payable for inpatient hospital services and post-hospital extended care services furnished an individual during a spell of illness. Section 1813(b)(2) of the act requires the Secretary to determine and publish, between July 1 and October 1 of each year, the amount of the inpatient hospital deductible for the following calendar year.

Under a formula in the law, the deductible for calendar year 1979 must be equal to $40 multiplied by the ratio of: (1) The current average rate for a day of inpatient hospital services for calendar year 1977 to (2) the average daily rate for such services in 1966. The amount so determined is rounded to the nearest multiple of $4. The average daily rates are determined by the Secretary based on the amounts paid on behalf of insured individuals to the hospitals participating in the medicare program plus the amounts withheld because of the deductible and coinsurance provisions.

Because the applicable coinsurance amounts in section 813 of the Social Secutity Act are fixed percentages of the inpatient deductible for services furnished in the same spell of illness, the increase in the deductible has the effect of also increasing the amount of coinsurance the Medicare beneficiary must pay. Thus, for spells of illness beginning in 1979, the daily coinsurance for the 61st through 90th days of hospitalization (one-fourth of the inpatient hospital deductible) will be $40; the daily coinsurance for lifetime reserve days (one-half the inpatient hospital deductible) will be $80; and the daily coinsurance for the 21st through the 100th days of extended care services (one-eighth of the inpatient hospital deductible) will be $20.

The data used to make the necessary computations of the current average daily rate for calendar years 1966 and 1977 are derived from individual inpatient hospital bills that are recorded for all beneficiaries in the records of the program. These records show, for each bill, the number of inpatient days of care and the interim cost (the sum of interim reimbursement, deductible, and coinsurance). Tabulations are prepared which summarize the data from these bills by the year in which the care was provided. The resulting average interim daily rate accurately reflects interim costs on an accrual basis.

In order to properly reflect the change in the average daily hospital cost under the program, the average interim cost (as shown in the tabulations) must be adjusted for the effect of final cost settlements made with each provider of services after the end of its accounting year to adjust the reimbursement to that provider from the amount paid during that year on an interim basis to the actual full cost of providing covered services to beneficiaries. To the extent that the ratio of final cost to interim cost for 1977 differs from the ratio of final cost to interim cost for 1966, the increase in average interim daily costs will not coincide with the increase in actual cost that has occurred.

The current average interim daily rate for inpatient hospital services for calendar year 1977, based on tabulated interim costs, is $155.26; the corresponding amount for 1966 is $37.92. These averages are based on approximately 93 million days of hospitalization in 1977 and 30 million days in 1966 (last 6 months of the year). The ratio of final cost to interim cost is approximately 1.035 for 1977 and 1.055 for 1966. Thus, the inpatient hospital deductible is $40\times[(155.26\times1.035)/(37.92\times1.055)]=\$160.67$, which is rounded to $160.

Dated: September 25, 1978.

JOSEPH A. CALIFANO, Jr.
Secretary.

[FR Doc. 78-27363 Filed 9-28-78 8:45 am]

[1505-01]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[AA-6703-A and AA-6703-B]

ALASKA NATIVE CLAIMS SELECTION

Correction

In FR Doc. 78-25189 appearing at page 40063, in the issue of Friday, September 8, 1978, on page 40064, first column, the first line immediately following T10 S.R.8 W., should be corrected to read, "Secs. 19 and 20 (fractional), all".

On page 40065, second column, in the fourth line of paragraph 6 change "613(c)" to read, "1613(c)".

[4310-84]

COPPER RIVER MERIDIAN, ALASKA

Filing of Plat of Survey

SEPTEMBER 19, 1978.

1. Plat of survey of the lands described below will be officially filed in the Alaska State Office, Anchorage, Alaska, effective at 10 a.m., November 10, 1978.

COPPER RIVER MERIDIAN, ALASKA

T. 10 N., R. 4 E.,
Sec. 25, lot 1, N½, SW¼, N½SE¼, SW¼SE¼;
Sec. 26, lots 1, 2, E½, NW¼, N½SW¼;
Sec. 27, all;
Sec. 34, all;
Sec. 35, lots 1 to 8 inclusive, NW¼NE¼, S½NW¼, SW¼, SW¼SE¼;
Sec. 36, lots 1 to 15 inclusive, NW¼NE¼, NE¼NW¼, SE¼.

Containing 3,574.90 acres.

2. The lands included in the foregoing survey are located about 2½ miles northeast of Chistochina, Alaska, on the Glenn Highway, and at the confluence of the Copper and Chistochina Rivers. Access into the area is by way of the Glenn Highway and a few gravel-surfaced and unimproved dirt roads. The elevation averages about 1,950 feet above sea level with the lands lying nearly level. The area is drained by the Copper and Chistochina Rivers, Boulder Creek, and a number of small feeder tributaries. The area is forested with spruce, cottonwood, and birch timber with willow, alder, low shrubs, and grasses as ground cover. The soil is generally a loam or sandy loam with some areas of muck.

Two surveyed claims are located in the area surveyed and these with the Glenn Highway, other roads, and an airport are the only improvements noted during the course of this survey.

No evidence of mineral was noted in the area.

The observed mean magnetic declination for the area is 29°30' E.

3. The public lands affected by this order are open to the operation of the public land laws, subject to any valid existing rights, the provisions of existing withdrawals, including Public Land Order 5418, filed March 28, 1974, and the requirements of applicable law, rules, and regulations.

4. Inquiries concerning the lands should be addressed to the State Director, Alaska State Office, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510.

Dated: September 20, 1978, Division of Cadastral Survey.

IRVING ZIRPEL, Jr.,
Chief, Division of Cadastral Survey.

[FR Doc. 78-27428 Filed 9-28-78; 8:45 am]

[4310-84]

COPPER MERIDIAN, ALASKA

Filing of Plat of Survey

SEPTEMBER 19, 1978.

1. Plat of survey of the lands described below will be officially filed in the Alaska State Office, Anchorage, Alaska, effective at 10 a.m., November 10, 1978.

COPPER RIVER MERIDIAN, ALASKA

T. 9 N., R. 4 E.,
Sec. 2, lots 1, 2, 3, 4, W½NE¼, W½;
Sec. 4, lots 1, 2, N½, SW¼, W½SE¼;
Sec. 5, all;
Sec. 6, lots 1, 2, 3, 4, E½, E½W½;
Sec. 7, lots, 1, 2, 3, 4, E½, E½W½;
Sec. 8, all;
Sec. 9, lots 1, 2, 3, NE¼NE¼, W½E½, W½;
Sec. 16, lots 1 to 18 inclusive, W½NW¼;
Sec. 17, lot 1, N½, SW¼, N½SE¼, SE¼SE¼;
Sec. 18, lots 1, 2, 3, 4, E½, E½W½;
Sec. 19, lots 1, 2, 3, N½NE¼, SW¼NE¼, E½NW¼;
Sec. 20, lots 1, 2, 3, 4, 5.
Containing 6,322.93 acres.

2. The lands embraced in this survey are located, for the most part, on the north side of the Copper River near Chistochina, Alaska. The area is drained by the Copper and Chistochina Rivers, the confluence of which is in section 2. The Copper River flows southwesterly along the southern part of the survey. A number of tributaries to the rivers makes up the total drainage pattern.

Elevations in the area range from about 1,800,000 feet above sea level to over 2,150 above sea level.

Improvements noted consist of the Glenn Highway, which is the means of access to the area, and a number of buildings and a landing strip at Chistochina in section 16. There is also a gravel pit in section 16.

No evidence of mineral or mineral activity was noted, other than the gravel pit.

The area is forested with spruce, birch, poplar, cottonwood, and aspen timber; with an understory of willow, other low brush, and grasses.

The mean magnetic declination is 29°30' E.

3. The public lands affected by this order are open to the operation of the public land laws, subject to any valid existing rights, the provisions of existing withdrawals, including Public Land Order 5418, filed March 28, 1974, and the requirements of applicable law, rules, and regulations.

4. Inquiries concerning the lands should be addressed to the State Director, Alaska State Office, 555 Cordova Street, Pouch 7-512, Anchorage, Alaska 99510.

Dated: September 20, 1978, Division of Cadastral Survey.

IRVING ZIRPEL, Jr.,
Chief, Division of Cadastral Survey.

[FR Doc. 78-27429 Filed 9-28-78; 8:45 am]

[4310-84]

[NM 34689]

NEW MEXICO

Application

SEPTEMBER 21, 1978.

Notice is hereby given that, pursuant to section 28 of the Mineral Leasing Act of 1920 (30 U.S.C. 185), as amended by the Act of November 16, 1973 (87 Stat. 576), Transwestern Pipeline Co. has applied for one 6-inch pipeline and related facilities right-of-way across the following land:

T. 18 S., R. 27 E., N. MEX. PRIN. MER., NEW MEXICO

Sec. 7, SW¼NE¼ and SE¼SE¼;
Sec. 17, W½SW¼;
Sec. 20, NW¼NW¼.

This pipeline will convey natural gas across 0.89 of a mile of public land in Eddy County, N. Mex.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved, and if so, under what terms and conditions.

Interested persons desiring to express their views should promptly send their name and address to the District Manager, Bureau of Land Management, P.O. Box 1397, Roswell, N. Mex. 88201.

FRED E. PADILLA,
Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-27486 Filed 9-28-78; 8:45 am]

[4310-84]

[NM 34688]

NEW MEXICO

Order Providing for Opening of Public Lands

SEPTEMBER 20, 1978.

1. In an exchange of lands made under the provisions of section 8 of the Act of June 28, 1934, 48 Stat. 1269, 1272, as amended and supplemented, 43 U.S.C. 315g (1970), the following described land has been reconveyed to the United States:

NEW MEXICO PRINCIPAL MERIDIAN, NEW MEXICO

T. 17 N., R. 4 W.,
Sec. 2. S½.

The area described contains 320 acres in Sandoval County.

2. Subject to valid existing rights, the provisions of existing withdrawals, and the requirements of applicable law, the lands described above are hereby open only for the purpose of consummating an exchange with the Navajo Tribe of Indians. The exchange program is to adjust Navajo Indian Land matters, including unauthorized occupancy and to stabilize Navajo Indian and non-Indian land use.

3. Inquiries concerning the lands should be addressed to Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, P.O. Box 1449, Santa Fe, N. Mex. 87501.

LARRY L. WOODWARD
Associate State Director.

[FR Doc. 78-27487 Filed 9-28-78; 8:45 am]

[4310-84]

[Wyoming 65064]

WYOMING

Application

SEPTEMBER 21, 1978.

Notice is hereby given that pursuant to section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185) Cities Service Gas Co. of Oklahoma City, Okla., filed an application for a 12¾-inch pipeline for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 18 N., R. 91 W.,
Sec. 6.
T. 18 N., R. 92 W.,
Secs. 10, 12, and 18.
T. 18 N., R. 93 W.,
Secs. 22 and 24.

The proposed pipeline will transport natural gas from a point in section 21, T. 18 N., R. 93 W., in a northeasterly direction to a point of connection with Cities Service Gas Co.'s gathering line in section 5, T. 18 N., R. 91 W., Carbon County, Wyo.

The purpose of this notice is to inform the public that the Bureau will be proceeding with consideration of whether the application should be approved and, if so, under what terms and conditions.

Interested persons desiring to express their views should do so promptly. Persons submitting comments should include their name and address and send them to the District Manager, Bureau of Land Management, P.O. Box 670, 1300 Third Street, Rawlins, Wyo. 82301.

WILLIAM S. GILMER,
Acting Chief, Branch of Lands and Minerals Operations.

[FR Doc. 78-27488 Filed 9-28-78; 8:45 am]

[4310-84]

[INT FES 78-22]

OUTER CONTINENTAL SHELF OFFSHORE THE MID-ATLANTIC STATES

Availability of Final Environmental Statement Regarding Proposed Oil and Gas Lease Sale No. 49

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a final environmental statement relating to a proposed Outer Continental Shelf (OCS) oil and gas lease sale of 136 tracts consisting of 313,344 hectares (774,273 acres) of submerged lands on the OCS in the Baltimore Canyon offshore the Mid-Atlantic States (OCS sale No. 49).

Single copies of the final environmental statement can be obtained from the Office of the Manager, New York Outer Continental Shelf Office, Bureau of Land Management, 26 Federal Plaza, Suite 32-120, New York, N.Y. 10007, and from the Office of Public Affairs, Bureau of Land Management (130), Washington, D.C. 20240.

Copies of the final environmental statement will also be made available for inspection in the following public libraries:

Massachusetts: Boston Public Library, Copley Square, Boston.
Rhode Island: Providence Public Library, 150 Empire Street, Providence.
Connecticut: Hartford Public Library, 500 Main Street, Hartford.
New York: Albany Public Library, Harmons Bleeker Building, 19 Dove Street, Albany; New York City Public Library, Fifth Avenue and 42d Street, New York; Nassau County Library System, Lower Concourse, Roosevelt Field, Garden City; and Suffolk County Cooperative Library System, 627 Sunrise Service Road, Bellport.
New Jersey: Trenton Free Library, 120 Academy Street, Trenton; Atlantic City Free Library, Illinois and Pacific Streets, Atlantic City; and Free Library of Elizabeth, 11 South Broad Street, Elizabeth.
Pennsylvania: Free Library of Philadelphia, Logan Circle, Philadelphia.
Delaware: Rehoboth Beach Public Library, Municipal Center, Rehoboth Avenue, Rehoboth Beach; and Wilmington Institute Free Library and Newcastle County Free Library, 10th and Market Streets, Wilmington.
Maryland: Eastern Shore Area Library, 122-126 South Division, Salisbury; and Enoch Pratt Free Library, 400 Cathedral Street, Baltimore.
Virginia: Norfolk Public Library System, 301 South City Hall Avenue, Norfolk.
North Carolina: Olivia Raney Public Library, 104 Fayetteville Street, Raleigh.

ARNOLD E. PETTY,
Acting Associate Director, Bureau of Land Management.

Approved:

LARRY E. MEIEROTTO,
Deputy Assistant Secretary of the Interior.

[FR Doc. 78-27484 Filed 9-28-78; 8:45 am]

[4310-84]

OUTER CONTINENTAL SHELF LEASE FORM

Revision of Form

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of revised OCS lease form.

SUMMARY: On September 5, 1978, the Bureau of Land Management published a proposed revision of the Outer Continental Shelf (OCS) lease form. A revision of the form is necessary in order to make the form consistent with the OCS Lands Act Amendments of 1978 (Pub. L. 95-372), which was signed into law by the President on September 18, 1978. The Bureau of Land Management has reviewed comments it received on the proposed lease form and adopts the lease form reprinted below.

DATE: This lease form is effective immediately and will be used for OCS sale No. 65 and, unless amended by public notice, for subsequent sales.

FOR FURTHER INFORMATION, CONTACT:

Chris Oynes, Bureau of Land Management, Department of the Interior, Washington, D.C. 20240, 202-343-2718.

SUPPLEMENTARY INFORMATION: The principal authors of the lease form are Charles Findlay, Office of the Solicitor, Chris Oynes, Bureau of Land Management, and Gerald Rhodes, U.S. Geological Survey.

Comments were received from 14 companies in writing and from 3 companies by telephone. Comments were also received from three Federal agencies. Several suggestions were adopted. Significant comments, as well as points most commonly made, are discussed below.

Many comments questioned whether section 2 includes the right to remove oil and gas from the leased area as was stated in the previous lease forms. This section of the lease form has been drafted to parallel as closely as possible sections 2(c) and 8(b)(4) of the OCS Lands Act Amendments of 1978 (hereafter referred to as the Act), which specify the rights conveyed by a lease. The right to remove oil and gas from the leasehold is inherent in the right to "produce" it, as is further suggested by section 8(a)(1) of the Act which requires payment of a royalty on oil and gas "saved, removed or sold." There are some new restrictions on the disposition of production imposed by the new Act and specified in section 15 of the lease form.

Several comments suggested that section 6(b) of the lease form should contain a sentence requiring notice and opportunity for a hearing as to the Geological Survey's determination of the value of production for royalty purposes. This sentence was contained in previous lease forms and is unnecessary in view of 30 CFR Part 290 which provides for appeals of decisions of the Geological Survey.

There were a number of suggestions that, in the first sentence of 6(b) of the lease form, the determination of the value of production for royalty purposes should be determined by the regulated price, if any, or that the regulated price should be taken into consideration. While the current lease

form in its reference to "the price received by the lessee * * * and * * * other relevant matters" already provides that the regulated price would be a consideration, the lease form has been amended so that the regulated price is specifically taken into consideration.

Pursuant to a recommendation by the Department of Energy, the third sentence of section 6(b) of the lease form has been amended. The amendment provides that the Geological Survey may, when the lessee has received special pricing relief from otherwise applicable Federal regulatory requirements, determine a value of production for royalty purposes which is less than the lessee received from the sale of the production. To accompany this change, a new sentence has been added to specify that the value of production, for purposes of computing royalty, can never be less than the fair market value in accordance with section 18(a)(4) of the Act.

There were a number of questions about the meaning of "other payments" in section 7 of the lease form. These words are intended to mean payments that would be due pursuant to some of the alternative bidding methods should the lease be issued by means of one of those methods. In response to the concern, the words have been changed to read "any payments required by this lease" to clarify that payments means obligations designated at the time of lease issuance.

Several comments noted that the new Act does not require development and production plans for lease operations in the Gulf of Mexico and that section 9 of the lease form should be amended accordingly. The Department has not yet determined whether or not its planned revision of 30 CFR 250.34 following passage of the new Act will continue to require development and production plans for the Gulf of Mexico. Section 9 of the lease form has therefore been amended by the addition of the words "as are required by regulation" in order to account for an election of either option.

Many companies recommended deletion or revision of section 12 of the lease form entitled "Safety Requirements." This section is taken almost verbatim from section 22(b) of the new Act which gives the Department little flexibility in making changes.

There were a number of suggestions for revising section 10 of the lease form which applies to performance. Many of the suggestions were to amend the section to conform with section 3(c) of the previous lease form. Section 10 of the new lease form is based on the previous version and other performance requirements including sections 5(a)(7) and 5(g) of the new Act and section 106 of the Energy Policy and Conservation Act.

Many comments remarked that section 16 of the lease form entitled "Unitization, Pooling and Drilling Agreements" is too brief and, most important, does not provide for a specific period within which a lessee may be required to subscribe to a unit agreement. That period, and other procedural requirements relating to unitization, are specified in the regulations and OCS order No. 11.

Finally, a few comments requested that the section in the previous lease form on heirs and successors be included in the new lease form. Inclusion of that section in the new lease form is unnecessary because a similar provision already appears in the regulations, 43 CFR 3307.6.

ARNOLD E. PETTY,
Acting Associate.

SEPTEMBER 26, 1978.

Form 3300-1
(September 1978)

UNITED STATES DEPARTMENT OF THE INTERIOR,
BUREAU OF LAND MANAGEMENT

OIL AND GAS LEASE OF SUBMERGED LANDS UNDER THE OUTER CONTINENTAL SHELF LANDS ACT

Office

_____

Serial Number

_____

Cash Bonus

_____

Rental Rate

_____

Minimum Royalty Rate

_____

Royalty Rate

_____

Work Commitment

_____

Profit Share Rate

_____

This lease is effective as of _____ (hereinafter called the "Effective Date") by and between the United States of America (hereinafter called the "Lessor"), by the _____, Bureau of Land Management, its authorized officer, and _____ (hereinafter called the "Lessee"). In consideration of any cash payment heretofore made by the Lessee to the Lessor and in consideration of the promises, terms, conditions, and covenants contained herein, including the stipulation(s) numbered _____ attached hereto, the lessee and Lessor agree as follows:

Sec. 1. *Statutes and Regulations.* This lease is issued pursuant to the Outer Continental Shelf Lands Act of August 7, 1953, 67 Stat. 462 as amended; 43 U.S.C. 1331 et seq. (hereinafter called the "Act"). The Lease is issued subject to the Act; sections 302 and 303 of the Department of Energy Organization Act, 91 Stat. 578-580, 42 U.S.C. 7152 and 7153; all regulations issued pursuant to such statutes and in existence upon the effective date of this lease; all regulations issued pursuant to such statutes in the future which provide for the prevention of waste and the conservation of the natural resources of the Outer Continental Shelf, and the protection of correlative rights therein; and all other applicable statutes and regulations.

Sec. 2. *Rights of Lessee.* The Lessor hereby grants and leases to the Lessee the exclusive right and privilege to drill for, develop and produce oil and gas resources, except helium gas, in the submerged lands of the Outer Continental Shelf described as follows:

_____

_____

_____

containing approximately —— acres or —— hectares (hereinafter referred to as the "leased area"). These rights include:

(a) the nonexclusive right to conduct within the leased area geological and geophysical explorations in accordance with applicable regulations;

(b) the nonexclusive right to drill water wells within the leased area, unless the water is part of geopressured-geothermal and associated resources, and to use the water produced therefrom for operations pursuant to the Act free of cost, on the condition that the drilling is conducted in accordance with procedures approved by the Director, or his delegate of the United States Geological Survey (hereinafter called the "Director"); and

(c) the right to construct or erect and to maintain within the leased area artificial islands, installations and other devices permanently or temporarily attached to the seabed and other works and structures necessary to the full enjoyment of the lease, subject to compliance with applicable laws and regulations.

Sec. 3. *Term.* This lease shall continue for an initial period of —— years from the Effective Date of the lease and so long thereafter as oil or gas is produced from the leased area in paying quantities, or drilling or well reworking operations, as approved by the Lessor, are conducted thereon.

Sec. 4. *Rentals.* The Lessee shall pay the Lessor, on or before the first day of each lease year, which commences prior to a discovery in paying quantities of oil or gas on the leased area, a rental of —— per acre (—— per hectare) or fraction thereof.

Sec. 5. *Minimum Royalty.* The Lessee shall pay the Lessor, at the expiration of each lease year which commences after a discovery of oil and gas in paying quantities, a minimum royalty of —— per acre (—— per hectare) or fraction thereof or, if there is production, the difference between the actual royalty required to be paid with respect to such lease year and the prescribed minimum royalty, if the actual royalty paid is less than the minimum royalty.

Sec. 6. *Royalty on Production.* (a) The Lessee shall pay a fixed royalty of —— percent in amount or value of production saved, removed or sold from the leased area. Gas of all kinds (except helium) is subject to royalty. The Lessor shall determine whether production royalty shall be paid in amount or value.

(b) The value of production for purposes of computing royalty on production from this lease shall never be less than the fair market value of the production. The value of production shall be the estimated reasonable value of the production as determined by the Lessor, due consideration being given to the highest price paid for a part or for a majority of production of like quality in the same field or area, to the price received by the Lessee, to posted prices, to regulated prices, and to other relevant matters. Except when the Lessor, in its discretion, determines not to consider special pricing relief from otherwise applicable Federal regulatory requirements, the value of production for the purposes of computing royalty shall not be deemed to be less than the gross proceeds accruing to the Lessee from the sale thereof. In the absence of good reason to the contrary, value computed on the basis of the highest price paid or offered at the time of production in a fair and open market for the major portion of like-quality products produced and sold from the field or area where the leased area is situated will be considered to be a reasonable value.

(c) When paid in value, royalties on production shall be due and payable monthly on the last day of the month next following the month in which the production is obtained, unless the Lessor designates a later time. When paid in amount, such royalties shall be delivered at pipeline connections or in tanks provided by the Lessee. Such deliveries shall be made at reasonable times and intervals and, at the Lessor's option, shall be effected either (i) on or immediately adjacent to the leased area, without cost to the Lessor, or (ii) at a more convenient point closer to shore or on shore, in which event the Lessee shall be entitled to reimbursement for the reasonable cost of transporting the royalty substance to such delivery point. The Lessee shall not be required to provide storage for royalty paid in amount in excess of tankage required when royalty is paid in value. When royalties are paid in amount, the Lessee shall not be held liable for the loss or destruction of royalty oil or other liquid products in storage from causes over which the Lessee has no control.

Sec. 7. *Payments.* The Lessee shall make all payments to the Lessor by check, bank draft, or money order unless otherwise provided by regulations or by direction of the Lessor. Rentals, royalties, and any other payments required by this lease shall be made payable to the United States Geological Survey and tendered to the Director, except that filing charges, bonuses, first year's rental and other payments due upon lease issuance, shall be made payable to the Bureau of Land Management and remitted to the appropriate field office of that Bureau.

Sec. 8. *Bonds.* The Lessee shall maintain at all times the bond(s) required by regulation prior to the issuance of the lease and shall furnish such additional security as may be required by the Lessor if, after operations or production have begun, the Lessor deems such additional security to be necessary.

Sec. 9. *Plans.* The Lessee shall conduct all operations on the leased area in accordance with approved exploration plans, and approved development and production plans as are required by regulations. The Lessee may depart from an approved plan only as provided by applicable regulations.

Sec. 10. *Performance.* The Lessee shall comply with all regulations and orders relating to exploration, development, and production. After due notice in writing, the Lessee shall drill such wells and produce at such rates as the Lessor may require in order that the leased area or any part thereof may be properly and timely developed and produced in accordance with sound operating principles.

Sec. 11. *Directional Drilling.* A directional well drilled under the leased area from a surface location on nearby land not covered by this lease shall be deemed to have the same effect for all purposes of the lease as a well drilled from a surface location on the leased area. In those circumstances, drilling shall be considered to have been commenced on the leased area when drilling is commenced on the nearby land for the purpose of directionally drilling under the leased area, and production of oil or gas from the leased area through any directional well surfaced on nearby land or drilling or reworking of any such directional well shall be considered production or drilling or reworking operations on the leased area for all purposes of the lease. Nothing contained in this paragraph shall be construed as granting to the Lessee any interest, license, easement, or other right in any nearby land.

Sec. 12. *Safety Requirements.* The lessee shall (a) maintain all places of employment within the leased area in compliance with occupational safety and health standards and, in addition, free from recognized hazards to employees of the Lessee or of any contractor or subcontractor operating within the leased area;

(b) Maintain all operations within the leased area in compliance with regulations intended to protect persons, property and the environment on the Outer Continental Shelf; and

(c) Allow prompt access, at the site of any operation subject to safety regulations, to any authorized Federal inspector and shall provide any documents and records which are pertinent to occupational or public health, safety or environmental protection as may be requested.

Sec. 13. *Suspension and Cancellation.* (a) The Lessor may suspend or cancel this lease during the initial lease term or thereafter pursuant to section 5 of the Act, and compensation shall be paid when provided by the Act.

(b) The Lessor may, upon recommendation of the Secretary of Defense, during a state of war or national emergency declared by the Congress or President of the United States, suspend operations under the lease, as provided in section 12(c) of the Act, and just compensation shall be paid to the Lessee for such suspension.

Sec. 14. *Indemnification.* The Lessee shall indemnify the Lessor for, and hold it harmless from, any claim including claims for loss or damage to property or injury to persons caused by or resulting from any operation on the leased area conducted by or on behalf of the Lessee. However, the Lessee shall not be held responsible to the Lessor under this subsection for any loss, damage or injury caused by or resulting from:

(a) Negligence of the Lessor other than the commission or omission of a discretionary function or duty on the part of a Federal agency whether or not the discretion involved is abused; or

(b) The Lessee's compliance with an order or directive of the Lessor against which an administrative appeal by the Lessee is filed before the cause of action for the claim arises and is pursued diligently thereafter.

Sec. 15. *Disposition of Production.* (a) As provided in section 27(a)(2) of the Act, the Lessor shall have the right to purchase not more than 16⅔ percent by volume of the oil and gas produced pursuant to the lease at the regulated price, or if no regulated price applies, at the fair market value at the well head of the oil and gas saved, removed, or sold, except that any oil or gas obtained by the Lessor as royalty or net profit share shall be credited against the amount that may be purchased under this subsection.

(b) As provided in section 27(d) of the Act, the Lessee shall take any Federal oil or gas for which no acceptable bids are received, as determined by the Lessor, and which is not transferred to a Federal agency pursuant to section 27(a)(3) of the Act, and shall pay to the Lessor a cash amount equal to the regulated price, or if no regulated price applies, the fair market value of the oil or gas so obtained.

(c) As provided in section 8(b)(7) of the Act, the Lessee shall offer 20 percent of the crude oil, condensate, and natural gas liquids produced on the lease, at the market value and point of delivery as provided by regulations applicable to Federal royalty oil to small or independent refiners as defined in the Emergency Petroleum Allocation Act of 1973.

(d) In the time of war, or when the President of the United States shall so prescribe, the Lessor shall have the right of first refusal to purchase at the market price all or any portion of the oil or gas produced from the leased area, as provided in section 12(b) of the Act.

Sec. 16. *Unitization, Pooling, and Drilling Agreements.* Within such time as the Lessor may prescribe, the Lessee shall subscribe to and operate under a unit, pooling or drilling agreement embracing all or part of the lands subject to this lease as the Lessor may determine to be appropriate or necessary. Where any provision of a unit, pooling or drilling agreement, approved by the Lessor, is inconsistent with a provision of this lease, the provision of the agreement shall govern.

Sec. 17. *Equal Opportunity Clause.* During the performance of this lease, the Lessee shall fully comply with paragraphs (1) through (7) of section 202 of Executive Order 11246 as revised (reprinted in 41 CFR 60-1.4(a)), and the implementing regulations, which are for the purpose of preventing employment discrimination against persons on the basis of race, color, religion, sex or national origin. Paragraphs (1) through (7) of section 202 of Executive Order 11246, as revised, are incorporated in this lease by reference.

Sec.18. *Certification of Nonsegregated Facilities.* By entering into this lease, the Lessee certifies, as specified in 41 CFR 60 1.8, that it does not and will not maintain or provide for its employees any segregated facilities at any of its establishments, and that it does not and will not permit its employees to perform their services at any location under its control where segregated facilities are maintained. As used in this certification, the term "segregated facilities" means, but is not limited to, any waiting rooms, work areas, rest rooms, and wash rooms, restaurants and other eating areas, time clocks, locker rooms, and other storage or dressing areas, parking lots, drinking fountains, recreation or entertainment areas, transporta-

tion, and housing facilities provided for employees which are segregated by explicit directive or are in fact segregated on the basis of race, color, religion, or national origin, because of habit, local custom, or otherwise. The Lessee further agrees that it will obtain identical certifications from proposed contractors and subcontractors prior to award of contracts or subcontracts unless they are exempt under 41 CFR 60-1.5.

Sec. 19. *Reservations to Lessor.* All rights in the leased area not expressly granted to the Lessee by the Act, the regulations, or this lease are hereby reserved to the Lessor without limiting the generality of the foregoing, reserved rights include:

(a) the right to authorize geological and geophysical exploration in the leased area which does not unreasonably interfere with or endanger actual operations under the lease, and the right to grant such easements or rights-of-way upon, through, or in the leased area as may be necessary or appropriate to the working of other lands or to the treatment and shipment of products thereof by or under authority of the Lessor;

(b) the right to grant leases for any minerals other than oil and gas within the leased area, except that operations under such leases shall not unreasonably interfere with or endanger operations under this lease;

(c) the right, as provided in Section 12(d) of the Act, to restrict operations in the leased area or any part thereof which may be designated by the Secretary of Defense, with the approval of the President, as being within an area needed for national defense, and so long as such designation remains in effect no operations may be conducted on the surface of the leased area or the part thereof included within the designation except with the concurrence of the Secretary of Defense. If operations or production under this lease within any designated area are suspended pursuant to this paragraph, any payments of rentals and royalty prescribed by this lease likewise shall be suspended during such period of suspension of operations and production, and the term of this lease shall be extended by adding thereto any such suspension period, and the Lessor shall be liable to the Lessee for such compensation as is required to be paid under the Constitution of the United States.

Sec. 20. *Transfer of Lease.* The Lessee shall file for approval with the appropriate field office of the Bureau of Land Management any instrument of assignment or other transfer of this lease, or any interest therein, in accordance with applicable regulations.

Sec. 21. *Surrender of Lease.* The Lessee may surrender this entire lease or any officially designated subdivision of the leased area by filing with the appropriate field office of the Bureau of Land Management a written relinquishment, in triplicate, which shall be effective as of the date of filing. No surrender of this lease or of any portion of the leased area shall relieve the Lessee or his surety of the obligation to pay all accured rentals, royalties and other financial obligations or abandon all wells on the area to be surrendered in a manner satisfactory to the Director.

Sec. 22. *Removal of Property on Termination of Lease.* Within a period of one year after termination of this lease in whole or in part, the Lessee shall remove all devices, works and structures from the premises no longer subject to the lease in accordance with applicable regulations and orders of the Director. However, the Lessee may, with the approval of the Director, continue to maintain devices, works and structures on the leased area for drilling or producing on other leases.

Sec. 23. *Remedies in Case of Default.* (a) Whenever the Lessee fails to comply with any of the provisions of the Act, the regulations issued pursuant to the Act or the terms of this lease, the lease shall be subject to cancellation in accordance with the provisions of section 5 (c) and (d) of the Act and the Lessor may exercise any other remedies which the Lessor may have, including the penalty provisions of section 24 of the Act. Furthermore, pursuant to section 8(o) of the Act, the Lessor may cancel the lease if it is obtained by fraud or misrepresentation.

(b) Nonenforcement by the Lessor of a remedy for any particular violation of the provisions of the Act, the regulations issued pursuant to the Act or the terms of this lease shall not prevent the cancellation of this lease or the exercise of any other remedies under paragraph (a) of this section for any other violation or for the same violation occurring at any other time.

Sec. 24. *Unlawful Interest.* No member of, or Delegate to, Congress, or Resident Commissioner, after election or appointment, or either before or after he has qualified, and during this continuance in office, and no officer, agent, or employee of the Department of the Interior, except as provided in 43 CFR Part 7, shall be admitted to any share or part in this lease or derive any benefit that may arise therefrom. The provisions of Section 3741 of the Revised Statutes as amended, 41 U.S.C. 22, and the Act of June 25, 1948, 62 Stat. 702 as amended, 18 U.S.C. 431-433, relating to contracts made or entered into, or accepted by or on behalf of the United States, from a part of this lease insofar as they may be applicable.

Lessee: _____
Authorized signature: _____
Name: _____
Title: _____
Date of signature: _____
Address of Lessee: _____

_____

United States of America, Lessor _____
Authorized signature: _____
Name: _____
Title: _____
Date: _____

_____

If this lease is executed by a corporation, it must bear the corporate seal.

[FR Doc. 78-27511 Filed 9-28-78; 8:45 am]

[4310-84]

Bureau of Land Management

OUTER CONTINENTAL SHELF, EASTERN GULF OF MEXICO

Outer Continental Shelf Leasing Systems Sale No. 65

Sec. 8(a)(8) (43 U.S.C. 1337(a)) of the Outer Continental Shelf Lands Act, as amended, requires that, at least 30 days before any lease sale, a notice be submitted to the Congress and published in the FEDERAL REGISTER.

(A) identifying the bidding systems to be used and the reasons for such use; and

(B) designating the tracts to be offered under each bidding system and the reasons for such designation.

This notice is published pursuant to these requirements.

Bidding systems to be used. In OCS lease sale 65, a system employing a cash bonus bid with a constant royalty fixed at 16⅔ percent will be used on 67 tracts. This system is authorized by section 8(a)(1)(A) of the OCS Lands Act, as amended. A system employing a cash bonus bid with a royalty established according to a semilogarithmic sliding scale will be used on 22 tracts. This system is authorized by section 8(a)(1)(C) of the OCS Lands Act, as amended. The use of the sliding scale royalty system was first introduced in OCS lease sale 43 and used again in OCS Lease Sale 45, as part of the commitment by the Department of the Interior and the Department of Energy to develop and test new biding systems.

The sliding scale is designed to establish higher royalty rates for larger resevoirs with higher production rates. This is intended to reduce bonuses, which should improve competition for leases. This would also tend to reduce the likelihood of production losses that could result if royalty rates are set by other means, such as royalty bidding at levels so high that production is made uneconomic.

The sliding scale used in recent lease sales (sales Nos. 43 and 45) was linear in form. Although this form is simple to depict, it has the disadvantage of creating an incentive to slow down production on very large reservoirs. The sliding scale to be tested in sale No. 65 is semilogarithmic in form and is intended to avoid incentives to slowdowns of production which may exist in other bidding systems.

The fixed sliding scale formula operates in the following way: When the quarterly value of production, adjusted for inflation, is less than or equal to $13.236229 million, a royalty of 16.66667 percent in amount or value of production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13.236230 million, but less than or equal to $1,662.854082 million, the royalty percent due on the unadjusted value or

amount of productin is given by the formula

$$R_j = b(Ln(V_j/S))$$

where

R_j = The percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 10.0

V_j = the value of production in quarter j, adjusted for inflation, in millions of dollars

S = 2.5

When the adjusted quarterly value of production is equal to or greater than $1,662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

The form of the sliding scale royalty schedule is illustrated in Figure 1. Note that the effective quarterly royalty rate depends upon the inflation adjusted quarterly value of production. However, this rate is applied to the unadjusted quarterly value of production to determine the royalty payments due.

In adjusting the quarterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding the issuance of the lease. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the actual amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.64. Table 1 provides hypothetical examples of quarterly royalty calculations using the sliding scale formula under two different values for the quarterly price index.

Figure 1
Form of the Sliding Royalty Schedule

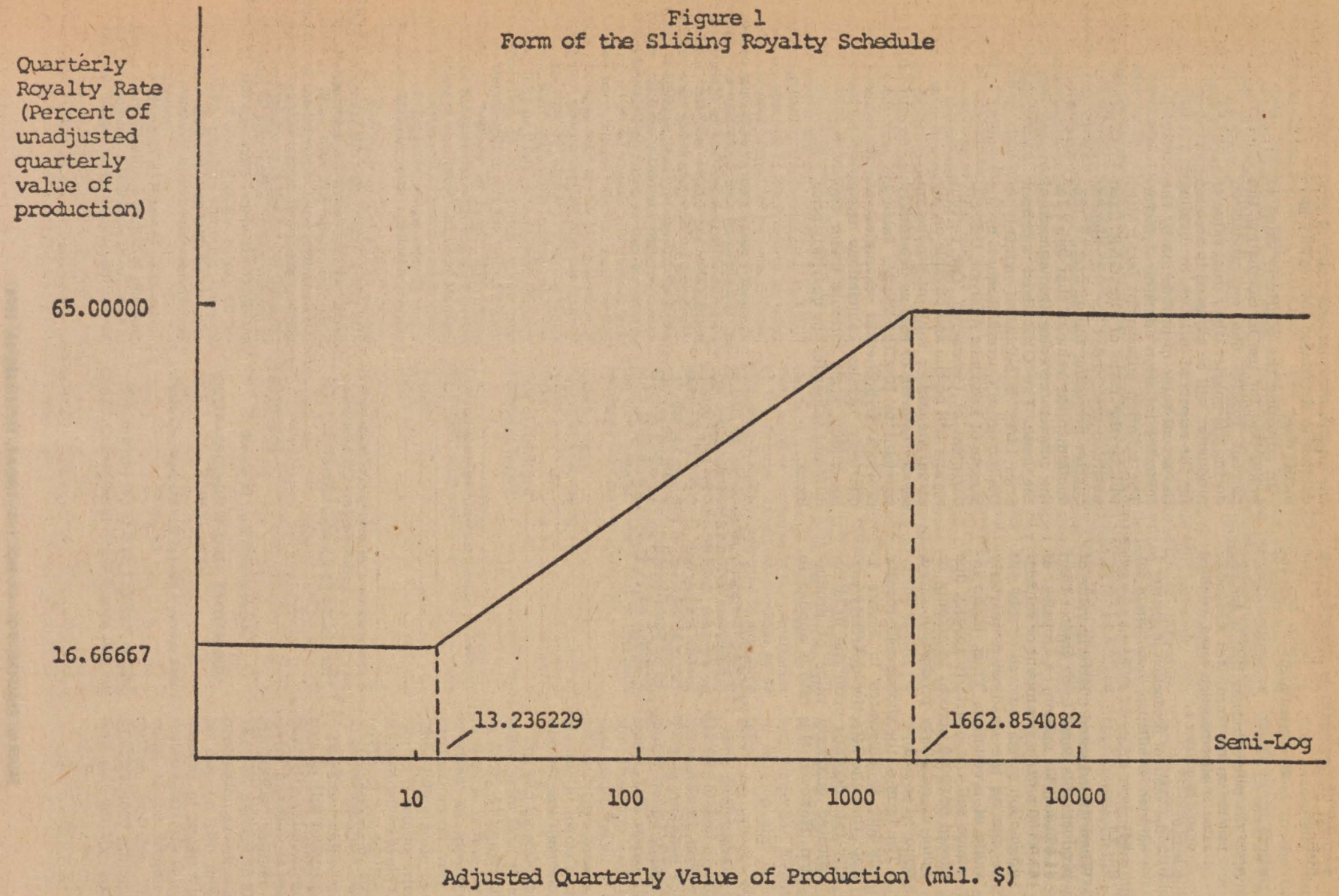

TABLE 1.—*Hypothetical Quarterly Royalty Calculations*

(1) Actual value of quarterly production (millions of dollars)	(2) GNP fixed weighted price index	(3) Inflation factor [1]	(4) Adjusted value of quarterly production [2] (V_i, millions of dollars)	(5) Percent royalty rate (R_i)	(6) Royalty payment [3] (millions of dollars)
10.000000	200.0	4/3	7.500000	16.66667	666667
30.000000	200.0	4/3	22.500000	21.97225	6.592675
90.000000	200.0	4/3	67.500000	32.95837	29.662533
270.000000	200.0	4/3	202.500000	43.94449	118.650123
810.000000	200.0	4/3	607.500000	54.93061	444.937941
10.000000	250.0	5/3	6.000000	16.66667	1.666667
30.000000	250.0	5/3	18.000000	19.74081	5.922243
90.000000	250.0	5/3	54.000000	30.72693	27.654237
270.000000	250.0	5/3	162.000000	41.71306	112.625262
810.000000	250.0	5/3	486.000000	52.69918	426.863358

[1] Column (2) divided by 150.0 (assumed value of GNP fixed weighted price index at time leases are issued).
[2] Column (1) divided by inflation factor.
[3] Column (1) times Column (5); All values are rounded for display purposes only.

The system employing cash bonus bids with a constant fixed royalty has been used extensively since the passage of the OCS Lands Act in 1953. Its use in sale No. 65 will provide data with which to compare the data from use of the sliding scale royalty system. The use of the two bidding systems in sale No. 65 is consistent with the requirements of sec. 8(a)(5)(B) of the OCS Lands Act, as amended.

Tracts to be offered under each bidding system. The 22 tracts marked with an asterisk (*) in the following list of tracts being offered are to be offered for cash bonus bid with royalty established according to a sliding scale of semi-logarithmic form. All other tracts are to be offered for cash bonus bid with constant royalty fixed at 16⅔ percent.

OCS OFFICIAL PROTRACTION DIAGRAM, PENSACOLA NH 16-5

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-1	882	All	5,760
65-2	883	All	5,760
65-3	884	All	5,760
65-4	885	All	5,760
65-5	886	All	5,760
65-6	926	All	5,760
65-7	927	All	5,760
65-8	928	All	5,760
65-9	929	All	5,760
65-10	930	All	5,760
65-11	970	All	5,760
65-12	971	All	5,760
65-13	972	All	5,760
65-14	973	All	5,760
65-15	974	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, DESTIN DOME NH 16-8

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-21	313	All	5,760.00
65-22	314	All	5,760.00
65-23	357	All	5,760.00
65-24	358	All	5,760.00
65-25*	473	All	5,760.00
65-26*	474	All	5,760.00
65-27*	518	All	5,760.00
65-28*	519	All	5,760.00

OCS OFFICIAL PROTRACTION DIAGRAM, DESTIN DOME NH 16-8—Continued

Tract No.	Block	Description	Acreage
65-29	529	All	5,760.00
65-30*	562	All	5,760.00
65-31*	563	All	5,760.00
65-32	573	All	5,454.72
65-33	574	All	5,760.00
65-34	618	All	5,760.00
65-35	661	All	5,760.00
65-36	662	All	5,760.00

OCS OFFICIAL PROTRACTION DIAGRAM, FLORIDA MIDDLE GROUND NH 16-12

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-41	358	All	5,760
65-42	359	All	5,760
65-48	402	All	5,760
65-49	403	All	5,760
65-50	404	All	5,760
65-51	405	All	5,760
65-57	446	All	5,760
65-58	447	All	5,760
65-63	490	All	5,760
65-64	491	All	5,760
65-69	534	All	5,760
65-70	535	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, THE ELBOW NG 16-3

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-71	567	All	5,134.56
65-72	609	All	5,760.00
65-73	696	All	5,760.00
65-74	697	All	5,760.00
65-75	739	All	5,760.00
65-76	783	All	5,760.00
65-77	827	All	5,760.00
65-78	871	All	5,760.00

OCS OFFICIAL PROTRACTION DIAGRAM, NG 16-6

[Approved June 5, 1974; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-79*	258	All	5,760
65-80*	259	All	5,760
65-81*	302	All	5,760
65-82*	303	All	5,760
65-83	609	All	5,760
65-84	610	All	5,760
65-85	611	All	5,760
65-86	653	All	5,760
65-87	654	All	5,760
65-88	697	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, TARPON SPRINGS NH 17-10

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-89*	233	All	5,760
65-90*	234	All	5,760
65-91*	277	All	5,760
65-92*	278	All	5,760
65-93*	279	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, ST. PETERSBURG NG 17-1

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-94*	661	All	5,760
65-95*	662	All	5,760
65-96*	705	All	5,760
65-97*	706	All	5,760
65-98	753	All	5,760
65-99	754	All	5,760
65-100	797	All	5,760
65-101	798	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, CHARLOTTE HARBOR NG 17-4

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-102	143	All	5,760
65-103	144	All	5,760
65-104	145	All	5,760
65-105	187	All	5,760
65-106	188	All	5,760
65-107*	221	All	5,760
65-108	231	All	5,760
65-109*	265	All	5,760
65-110*	266	All	5,760
65-111	627	All	5,760
65-112	628	All	5,760
65-113	671	All	5,760
65-114	672	All	5,760
65-115	715	All	5,760
65-116	716	All	5,760

The selection of tracts to be offered under the sliding scale royalty system was made for the following reasons:

1. A sufficient number of tracts was needed to provide data for valid statistical analysis while limiting the risk of losses caused by unforeseen problems which could arise in the use of any new bidding system. A sample size of approximately 25 percent or 22 tracts was determined to be appropriate.

2. All tracts on an identifiable geological structure were to be offered under the same bidding system to reduce problems that could arise from managing adjacent tracts under different financial terms and to assure that bidding and production decisions

would be clearly attributable to one bidding system or the other.

3. The range and distribution of the characteristics of sliding scale royalty tracts were to match, as closely as possible, the range and distribution of the characteristics of the tracts being offered in the sale. Such characteristics include estimated resources, water depth, structure depth, favorable vs. unfavorable location of tracts on structures, and the distribution of tracts across trends.

Dated: September 22, 1978.

ARNOLD E. PETTY,
Acting Associate Director,
Bureau of Land Management.

Approved:

HEATHER L. ROSS,
Deputy Assistant Secretary
of the Interior.

[FR Doc. 78-27233 Filed 9-28-78; 8:45 am]

[4310-84]

OUTER CONTINENTAL SHELF—GULF OF MEXICO

Oil and Gas Lease Sale No. 65

1. *Authority.* This notice is published pursuant to the Outer Continental Shelf Lands Act (43 U.S.C. 1331-1343) as amended, and the regulations issued thereunder (43 CFR Part 3300).

Filing of bids. Sealed bids will be received by the Manager, New Orleans Outer Continental Shelf (OCS) Office, Bureau of Land Management, Hale Boggs Federal Building, 500 Camp Street, Suite 841, New Orleans, La. 70130. Bids may be delivered, either by mail or in person, to the above address until 4:15 p.m., c.s.t., October 30, 1978, or by personal delivery to the Tulane Room, Grand Hotel, 1500 Canal Street, New Orleans, La. 70140, between the hours of 8:30 a.m., c.s.t., and 9:30 a.m. c.s.t., October 31, 1978. Bids received by the Manager later than the times and dates specified above will be returned unopened to the bidders. Bids may not be modified or withdrawn unless written modification or withdrawal is received by the Manager prior to 9:30 a.m., c.s.t., October 31, 1978. All bids must be submitted and will be considered in accordance with applicable regulations, including 43 CFR Part 3300. The list of restricted joint bidders which applies to this sale was published in 43 FR 15500, April 13, 1978, as corrected in 43 FR 16427, April 18, 1978.

3. *Method of bidding.* A separate bid in a sealed envelope, labeled "Sealed Bid for Oil and Gas Lease (insert number of tract), not to be opened until 10 a.m., c.s.t., October 31, 1978," must be submitted for each tract. A suggested form appears in paragraph 17 of this notice. Bidders are advised that tract numbers are assigned solely for administrative purposes and are not the same as block numbers found on offical protraction diagrams. All bids received shall be deemed submitted for a numbered tract. Bidders must submit with each bid one-fifth of the cash bonus in cash or by casher's check, bank draft, certified check, or money order payable to the order of the Bureau of Land Management. No bid for less than a full tract as described in paragraph 13 will be considered. Bidders subinitting joint bids must state on the bid form the proportionate interest of each participating bidder, in percent to a maximum of five decimal places, as well as submit a sworn statement that the bidder is qualified under 43 CFR Part 3302. The suggested form for this statement to be used in joint bids appears in paragraph 18. Other documents may be required of bidders under 43 CFR 3302.4. Bidders are warned against violation of 18 U.S.C. 1860, prohibiting unlawful combination or intimidation of bidders.

4. *Bonus bidding with a fixed sliding scale royalty.* Bids on tracts 65-25, 65-26, 65-27, 65-28, 65-30, 65-31, 65-79, 65-80, 65-81, 65-82, 65-89, 65-90, 65-91, 65-92, 65-93, 65-94, 65-95, 65-96, 65-97, 65-107, 65-109, and 65-110 must be submitted on a cash bonus bid basis with the percent royalty due in amount or value of production saved, removed or solid fixed according to the sliding scale formula described below. This formula fixes the percent royalty at a level determined by the value of lease production during each calendar quarter. For purposes of determining the royalty percent due on production during a quarter, the value of production during the quarter will be adjusted for inflation as described below. The determination of the value of the production on which royalty is due will be made pursuant to 30 CFR 250.64.

The fixed sliding scale formula operates in the following way: when the quarterly value of production, adjusted for inflation, is less than or equal to $13.236229 million, a royalty of 16.66667 percent in amount or value of production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13.236230 million, but less than or equal to $1662.854082 million, the royalty percent due on the unadjusted value or amount of production is given by

$$R_j = b[\mathrm{Ln}\,(V_j/S)]$$

where

R_j = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 10.0

Ln = natural logarithm

V_j = the value of production in quarter j, adjusted for inflation, in millions of dollars

S = 2.4

When the adusted quarterly value of production is equal to or greater than $1662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

In determining the quarterly percent royalty due, R_j, the calculation will be carried to five decimal places (for example, 20.17329 percent.) This calculation will incorporate the adjusted quarterly value of production, V_j, in millions of dollars, rounded to the sixth digit, i.e., to the nearest dollar (for example, 15.392847 millions of dollars).

The form of the sliding scale royalty schedule is illustrated in Figure 1. Note that the effective quarterly royalty rate depends upon the inflation adjusted quarterly value of production. However, this rate is applied to the unadjusted quarterly value of production to determine the royalty payments due.

In adjusting the quaterly value of production for use in calculating the percent royalty due on production during the quarter, the actual value of production will be adjusted to account for the effects of inflation by dividing the actual value of production by the following inflation adjustment factor. The inflation adjustment factor used will be the ratio of the GNP fixed weighted price index for the calendar quarter preceding the quarter of production to the value of that index for the quarter preceding the issuance of the lease. The GNP fixed weighted price index is published monthly in the Survey of Current Business by the Bureau of Economic Analysis, U.S. Department of Commerce. The percent royalty will be due and payable on the acutal amount or value of production saved, removed, or sold as determined pursuant to 30 CFR 250.64. The timing of procedures for inflation adjustments and determinations of the royalty due will be specified at a later date. Table 1 provides hypothetical examples of quarterly royalty calculations using the sliding scale formula just described under two differents values for the quarterly price index.

Leases awarded on the basis of a cash bonus bid with fixed sliding scale royalty will provide for a yearly rental or minimum royalty payment of $3 per acre or fraction thereof.

Bidders for these tracts should recognize that the Department of Energy is authorized, under section 302(b) and (c) of the Department of Energy Organization Act, to establish production rates for all Federal oil and gas leases.

Figure 1
Form of the Sliding Royalty Schedule

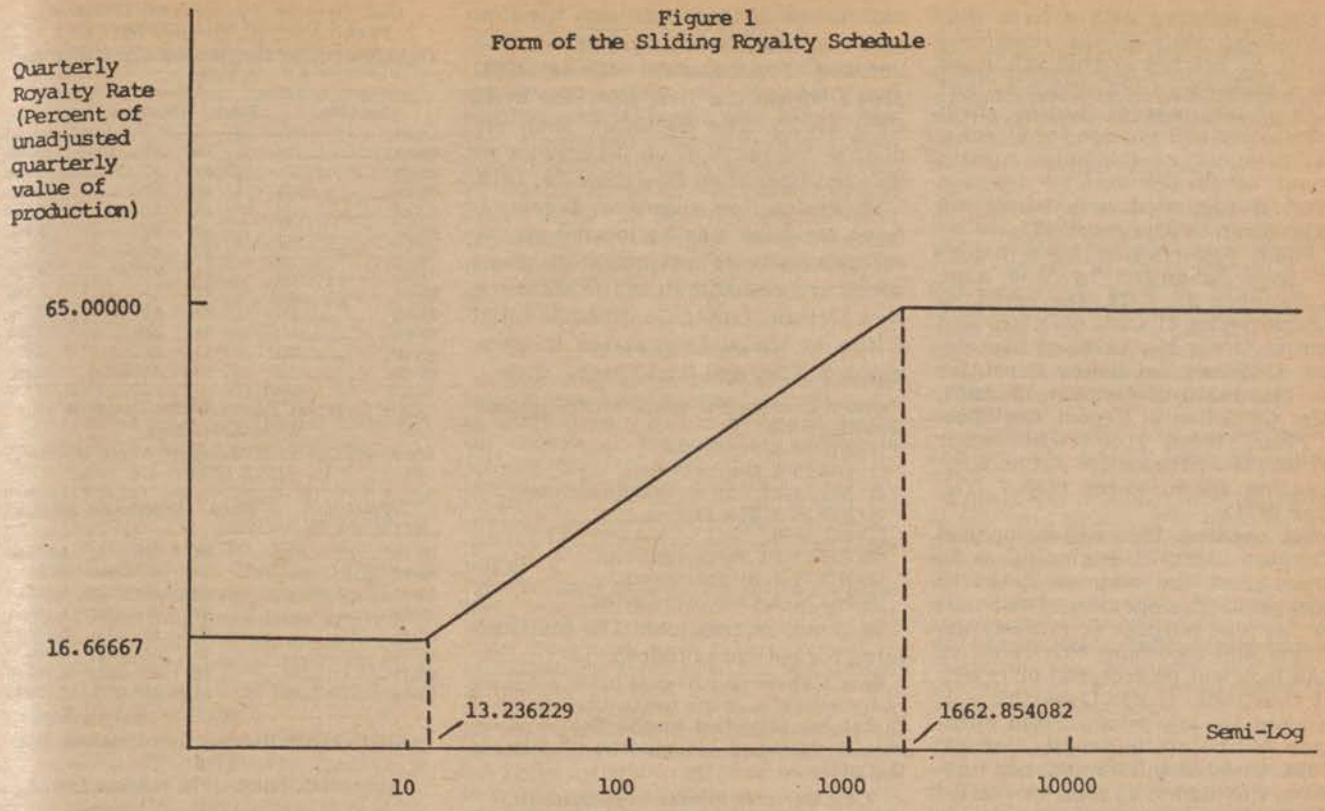

TABLE 1.—*Hypothetical Quarterly Royalty Calculations*

(1) Actual value of quarterly production (millions of dollars)	(2) GNP fixed weighted price index	(3) Inflation factor [1]	(4) Adjusted value of quarterly production [2] (v_i, millions of dollars)	(5) Percent royalty rate (R_i)	(6) Royalty payment [3] (millions of dollars)
10.000000	200.0	⅓	7.500000	16.66667	1.666667
30.000000	200.0	⅓	22.500000	21.97225	6.591675
90.000000	200.0	⅓	67.500000	32.95837	29.662533
270.000000	200.0	⅓	202.500000	43.94449	118.650123
810.000000	200.0	⅓	607.500000	54.93061	444.937941
10.000000	250.0	⅔	6.000000	16.66667	1.666667
30.000000	250.0	⅔	18.000000	19.74081	5.922243
90.000000	250.0	⅔	54.000000	30.72693	27.654237
270.000000	250.0	⅔	162.000000	41.71306	112.625262
810.000000	250.0	⅔	486.000000	52.69918	426.863358

[1] Column (2) divided by 150.0 (assumed value of GNP fixed weighted price index at time leases are issued).
[2] Column (1) divided by inflation factor.
[3] Column (1) times column (5); all values are rounded for display purposes only.

5. *Bonus bidding with a fixed constant royalty.* Bids on the remaining tracts to be offered at this sale must be on a cash bonus basis with a fixed royalty of 16⅔ percent. Leases which may be issued will provide for a yearly rental payment or minimum royalty payment of $3 per acre or fraction thereof. A suggested cash bonus bid form is shown in paragraph 17.

6. *Equal opportunity.* Each bidder must have submitted by 9:30 a.m., c.s.t., October 31, 1978, the certification required by 41 CFR 60-1.7(b) and Executive Order No. 11246 of September 24, 1965, as amended by Executive Order No. 11375 of October 13, 1967, on the Compliance Report Certification Form, Form 1140-8 (November 1973), and the Affirmative Action Representation Form, Form 1140-7 (December 1971).

7. *Bid opening.* Bids will be opened on October 31, 1978, beginning at 10 a.m., c.s.t., at the address stated in paragraph 2. The opening of the bids is for the sole purpose of publicly announcing and recording bids received, and no bids will be accepted or rejected at that time. If the Department is prohibited for any reason from opening any bid before midnight, October 31, 1978, that bid will be returned unopened to the bidder, as soon thereafter as possible.

8. *Deposit of payments.* Any cash, cashier's checks, certified checks, bank drafts, or money orders submitted with a bid may be deposited in a suspense account in the Treasury during the period the bids are being considered. Such a deposit does not constitute and shall not be construed as acceptance of any bid on behalf of the United States.

9. *Acceptance or rejection of bids.* The United State reserves the right to reject any and all bids for any tract. In any case, no bid for any tract will be accepted and no lease for any tract will be awarded to any bidder unless:

(a) The bidder has complied with all requirements of this notice and applicable regulations;

(b) The bid is the highest valid cash bonus bid; and

(c) The amount of the bid has been determined to be adequate by the Secretary of the Interior.

No bid will be considered for acceptance unless it offers a cash bonus in the amount of $25 or more per acre or fraction thereof.

10. *Withdrawal of tracts.* The United States reserves the right to withdraw any tract from this sale prior to issuance of a written acceptance of a bid for that tract.

11. *Successful bidders.* Each person who has submitted a bid accepted by the Secretary of the Interior will be required to execute copies of the lease specified below, pay the balance of the cash bonus bid together with the first year's annual rental, and satisfy the bonding requirements of 43 CFR 3304.1 within the time provided in 43 CFR 3302.5. The Secretary shall announce his decision on acceptance of bids not later than December 29, 1978.

12. *Protraction diagrams.* Tracts offered for lease may be located on the following official protraction diagrams which are available from the Manager, New Orleans Outer Continental Shelf Office at the address stated in paragraph 2. They sell for $2 each.

Outer Continental Shelf offical protraction diagrams:

(1) NH 16-5, Pensacola.
(2) NH 16-8, Destin Dome.
(3) NH 16-12, Florida Middle Ground.
(4) NG 16-3, The Elbow.
(5) NG 16-6.
(6) NH 17-10, Tarpon Springs.
(7) NG 17-1, St. Petersburg.
(8) NG 17-4, Charlotte Harbor.

13. *Tract descriptions.* The tracts offered for bid are as follows:

NOTE.—There may be gaps in the sequence of the numbers of the tracts listed. Some of the blocks identified in the final environmental statement may not be included in this notice.

OCS OFFICIAL PROTRACTION DIAGRAM, PENSACOLA NH 16-5

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-1	882	All	5,760
65-2	883	All	5,760
65-3	884	All	5,760
65-4	885	All	5,760
65-5	886	All	5,760
65-6	926	All	5,760
65-7	927	All	5,760
65-8	928	All	5,760
65-9	929	All	5,760
65-10	930	All	5,760
65-11	970	All	5,760
65-12	971	All	5,760
65-13	972	All	5,760
65-14	973	All	5,760
65-15	974	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, DESTIN DOME NH 16-8

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-21	313	All	5,760.00
65-22	314	All	5,760.00
65-23	357	All	5,760.00
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65-25	473	All	5,760.00
65-26	474	All	5,760.00
65-27	518	All	5,760.00
65-28	519	All	5,760.00
65-29	529	All	5,760.00
65-30	562	All	5,760.00
65-31	563	All	5,760.00
65-32	573	All	5,454.72
65-33	574	All	5,760.00
65-34	618	All	5,760.00
65-35	661	All	5,760.00
65-36	662	All	5,760.00

OCS OFFICIAL PROTRACTION DIAGRAM, FLORIDA MIDDLE GROUND NH 16-12

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-41	358	All	5,760
65-42	359	All	5,760
65-48	402	All	5,760
65-49	403	All	5,760
65-50	404	All	5,760
65-51	405	All	5,760
65-57	446	All	5,760
65-58	447	All	5,760
65-63	490	All	5,760
65-64	491	All	5,760
65-69	534	All	5,760
65-70	535	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, THE ELBOW NG 16-3

[Approved Oct. 10, 1972; Revised Aug. 1, 1973; Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-71	567	All	5,134.56
65-72	609	All	5,760.00
65-73	696	All	5,760.00
65-74	697	All	5,760.00
65-75	739	All	5,760.00
65-76	783	All	5,760.00
65-77	827	All	5,760.00
65-78	871	All	5,760.00

OCS OFFICIAL PROTRACTION DIAGRAM, NG 16-6

[Approved June 5, 1974; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-79	258	All	5,760
65-80	259	All	5,760
65-81	302	All	5,760
65-82	303	All	5,760
65-83	609	All	5,760
65-84	610	All	5,760
65-85	611	All	5,760
65-86	653	All	5,760
65-87	654	All	5,760
65-88	697	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, TARPON SPRINGS NH 17-10

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-89	233	All	5,760
65-90	234	All	5,760
65-91	277	All	5,760
65-92	278	All	5,760
65-93	279	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, ST. PETERSBURG NG 17-1

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-94	661	All	5,760
65-95	662	All	5,760
65-96	705	All	5,760
65-97	706	All	5,760
65-98	753	All	5,760
65-99	754	All	5,760
65-100	797	All	5,760
65-101	798	All	5,760

OCS OFFICIAL PROTRACTION DIAGRAM, CHARLOTTE HARBOR NG 17-4

[Approved Oct. 10, 1972; Revised Dec. 2, 1976]

Tract No.	Block	Description	Acreage
65-102	143	All	5,760
65-103	144	All	5,760
65-104	145	All	5,760
65-105	187	All	5,760
65-106	188	All	5,760
65-107	221	All	5,760
65-108	231	All	5,760
65-109	265	All	5,760
65-110	266	All	5,760
65-111	627	All	5,760
65-112	628	All	5,760
65-113	671	All	5,760
65-114	672	All	5,760
65-115	715	All	5,760
65-116	716	All	5,760

14. *Lease terms and stipulations.* All leases issued as a result of this sale will be for an initial term of 5 years. Leases issued as a result of this sale will be on Form 3300-1 (September 1978), available from the Manager, New Orleans Outer Continental Shelf Office, at the address stated in paragraph 2. For leases resulting from this sale for tracts offered on a cash bonus basis with fixed sliding scale royalty, listed in paragraph 4, Form 3300-1 will be amended as follows:

Sec. 6. *Royalty on production.* (a) To pay the lessor a royalty of that percent in amount or value of production saved, removed or sold from the leased area as determined by the sliding scale royalty formula as follows. When the quarterly value of production, adjusted for inflation, is less than or equal to $13.236229 million, a royalty of 16.66667 percent in amount or value of production saved, removed or sold will be due on the unadjusted value or amount of production. When the adjusted quarterly value of production is equal to or greater than $13.236230 million, but less than or equal to $1662.854082 million, the royalty percent due on the unadjusted value or amount of production is given by

$$R_j = b[\mathrm{Ln}\,(V_j/S)]$$

where

R_j = the percent royalty that is due and payable on the unadjusted amount or value of all production saved, removed or sold in quarter j

b = 10.0

Ln = natural logarithm

V_j = the value of production in quarter j, adjusted for inflation, in millions of dollars

S = 2.5

When the adjusted quarterly value of production is equal to or greater than $1662.854083 million, a royalty of 65.00000 percent in amount or value of production saved, removed or sold will be due on the unadjusted quarterly value of production. Thus, in no instance will the quarterly royalty due exceed 65.00000 percent in amount or value of quarterly production saved, removed or sold.

In determining the quarterly percent royalty due, R_j, the calculation will be carried to five decimal places (for example, 20.17329 percent). This calculation will incorporate the adjusted quarterly value of production, V_j, in millions of dollars, rounded to the sixth digit, i.e., to the nearest dollar (for example, 15.392847 millions of dollars). . . .

In the following stipulation the term Supervisor refers to the Gulf of Mexico area Oil and Gas Supervisor for Operations of the Geological Survey and the term Manager refers to the Manager of the New Orleans OCS Office of the Bureau of Land Management. Except as otherwise noted, the following stipulations will be included in each lease resulting from this sale.

STIPULATION No. 1

a. The lessee agrees that if any site, structure, or object of historical or archaeological significance should be discovered during the conduct of operations on any leased area, he shall report immediately such findings to the Supervisor, and make every reasonable effort to preserve and protect the cultural resource from damage until the Supervisor has given directions as to its preservation.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-1 through 65-15, 65-21, 65-89 through 65-93.)

For these lease tracts, falling within Cultural Resource Zones 1 and 2 as defined and plotted in the final report Cultural Resources Evaluation of the Northern Gulf of Mexico Continental Shelf (Coastal Environments, Inc., 1977), and tracts falling outside the Zones 1 and 2 in which there is reason to believe a cultural resource exists, the Supervisor shall require the lessee to comply with the following:

Prior to any drilling activity or the construction or placement of any structure for exploration or development on the lease, including but not limited to, well drilling and pipeline and platform placement, hereinafter in this stipulation referred to as "operation", the lessee shall conduct remote sensing surveys to determine the potential existence of any cultural resource that may be affected by such operations. All data produced by such remote sensing surveys as well as other pertinent natural and cultural environmental data shall be examined by a qualified marine survey archaeologist to determine if indications are present suggesting the existence of a cultural resource that may be adversely affected by any lease operation. A report of this survey and assessment prepared by the marine survey archaeologist shall be submitted by the lessee to the Supervisor and to the Manager.

If such cultural resource indicators are present the lessee shall: (1) Locate the site of such operations so as not to adversely affect the identified location; or (2) establish, to the satisfaction of the Supervisor, on the basis of further archaeological investigation conducted by a qualified marine survey archaeologist or underwater archaeologist using such survey equipment and techniques as deemed necessary by the Supervisor, either that such operations will not adversely affect the location identified or that the potential cultural resource suggested by the occurrence of the indicators does not exist.

A report of this investigation prepared by the marine survey archaeologist or underwater archaeologist shall be submitted to the Supervisor and the Manager, for their review. Should the Supervisor determine that the existence of a cultural resource which may be adversely affected by such operation is sufficiently established to warrant protection, the lessee shall take no action that may result in an adverse effect on such cultural resource until the Supervisor has given directions as to its preservation.

STIPULATION No. 2

For the purpose of this stipulation, "Live Bottom Areas" are defined as those areas which contain biological assemblages consisting of such sessile invertebrates as sea fans, sea whips, hydroids, anemones, ascidians, sponges, bryozoans, or corals living upon and attached to naturally occurring hard or rocky formations with rough, broken, or smooth topography; or whose lithotope favors the accumulation of turtles and fishes.

a. (To apply only to leases resulting from this proposed sale for tracts 65-1 through 65-15.)

Prior to any drilling activity or placement of any fixed structures or pipelines or any other exploration or production activity, the lessee will submit to the Supervisor as part of his exploration and/or development plan a bathymetry map, prepared utilizing remote sensing survey techniques. This map will include interpretations for the presence of live bottom areas within a minimum one-mile radius of the proposed exploration or production activity site.

b. (To apply to all leases resulting from this proposed sale.)

If it is determined that remote sensing data indicate the possibility of live bottom areas, the lessee will submit to the Supervisor photo or other documentation of the sea bottom of the proposed exploratory drilling sites or proposed platform locations or points as determined by the Supervisor.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor will require the lessee to undertake any measures deemed economically, environmentally, and technologically feasible to protect live bottom areas. These measures may include, but are not limited to, the following:

1. The relocation of operations to avoid live bottom areas.

2. The shunting of all drilling fluids and cuttings in such a manner as to avoid live bottom areas.

3. The transportation of drilling fluids and cuttings to approved disposal sites.

4. The monitoring of live bottom areas to assess the adequacy of any mitigating measures taken and the impact of lessee-initiated activities.

STIPULATION No. 3

a. (To apply only to the leases resulting from this proposed sale for tracts 65-1, 65-6, 65-11, 65-12, 65-21 through 65-28, 65-30, 65-31, 65-41 through 65-70, 65-73 through 65-78, and 65-94 through 65-116.)

Whether or not compensation for such damage or injury might be due under a theory of strict or absolute liability or otherwise, the lessee assumes all risks of damage or injury to persons or property, which occur in, on, or above the Outer Continental Shelf, to any persons or to any property of any person or persons who are agents, employees or invitees of the lessee, its agents, independent contractors or subcontractors doing business with the lessee in connection with any activities being performed by the lessee in, on, or above the

Outer Continental Shelf, if such injury or damage to such person or property occurs by reason of the activities of any agency of the U.S. Government, its contractors or subcontractors, or any of their officers, agents or employees, being conducted as a part of, or in connection with the programs and activities of the Gulf Test Range, the Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, Tyndall Air Force Base or Naval Air Advance Training Command, Naval Air Station, Corpus Christi, Texas. The lessee assumes this risk whether such injury or damage is caused in whole or in part by any act or ommission, regardless of negligence or fault, of the United States, its contractors or subcontractors, or any of their officers, agents, or employees. The lessee further agrees to indemnify and save harmlesss the United States against and to defend at its own expense the United States against all claims for loss, damage, or injury sustained by the lessee, and to indemnify and save harmless the United States against, and to defend at its own expense the United States against, all claims for loss, damage, or injury sustained by the agents, employees, or invitees of the lessee, its agents, or any independent contractors or subcontractors doing business with the lessee in connection with the programs and activities of the aforementioned military installations, whether the same be caused in whole or in part by the negligence or fault of the United States, its contractors, or subcontractors, or any of their officers, agents, or employees and whether such claims might be sustained under theories of strict or absolute liability or otherwise.

The lessee agrees to control his own electromagnetic emissions and those of his agents, employees, invitees, independent contractors or subcontractors emanating from individual designated defense warning areas in accordance with requirements specified by the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, or Tyndall Air Force Base, to the degree necessary to prevent damage to, or unacceptable interference with, Department of Defense flight, testing or operational activities, conducted within individual designated warning areas. Necessary monitoring control, and coordination with the lessee, his agents, employees, invitees, independent contractors or subcontractors, will be effected by the commander of the appropriate onshore military installation conducting operations in the particular warning area; provided, however, that control of such electromagnetic emissions shall in no instance prohibit all manner of electromagnetic communication during any period of time between a lessee, its agents, employees, invitees, independent contractors or subcontractors and onshore facilities.

The lessee, when operating or causing to be operated on its behalf boat or aircraft traffic into the individual designated warning areas shall enter into an agreement with the commander of the appropriate onshore military installation, i.e., Pensacola Naval Air Station, Eglin Air Force Base, MacDill Air Force Base, or Tyndall Air Force Base, utilizing an individual designated warning area prior to commencing such traffic. Such agreement will provide for positive control of boats and aircraft operating into the warning areas at all times.

b. (To apply only to the leases resulting from this proposed sale for tracts 65-25 through 65-28, 65-30, and 65-31.)

When the activities of the Armament Development and Test Center at Eglin Air Force Base may endanger personnel or property, the lessee agrees, upon receipt of a directive from the Secretary, to evacuate all personnel from all structures on the lease and to shut-in and secure all wells and other equipment, including pipelines on the lease, within forty-eight (48) hours or within such longer period as may be specified by the directive. Such directive shall not require evacuation of personnel and shutting-in and securing of equipment for a period of time greater than seventy-two (72) hours; however, such period of time may be extended by subsequent directive from the Secretary. Equipment and structures may remain in place on the lease during such time as the directive remains in effect.

STIPULATION No. 4

Pipelines will be required, (1) if pipeline rights-of-way can be determined and obtained, (2) if laying such pipelines is technologically feasible and environmentally preferable, and (3) if, in the opinion of the lessor, pipelines can be laid without net social loss, taking into account any incremental costs of pipelines over alternative methods of transportation and any incremental benefits in the form of increased environmental protection or reduced multiple use conflicts, The lessor specifically reserves the right to require that any pipeline used for transporting production to shore be placed in certain designated management areas. In selecting the means of transportation, consideration will be given to any recommendation of the Intergovernmental Planning Program for Leasing and Management of Transportation of Outer Continental Shelf Oil and Gas with the participation of Federal, State, and local government and the industry. Where feasible, all Department of the Interior regulated pipelines, including both flow lines and gathering lines for oil and gas, shall be buried to a depth suitable for adequate protection from water currents, sand waves, storm scouring, fisheries trawling gear, and other uses as determined on a case-by-case basis.

Following the completion of pipeline installations, no crude oil production will be transported by surface vessel from offshore production sites, except in the case of emergency. Determinations as to emergency conditions and appropriate responses to these conditions will be made by the Supervisor. Where the three criteria set forth in the first sentence of this stipulation are not met and surface transportation must be employed:

All vessels used for carrying hydrocarbons to shore from the leased area will conform with all standards established for such vessels, pursuant to the Ports and Waterways Safety Act of 1972 (46 U.S.C. 391a).

STIPULATION No. 5

To be included in any leases resulting from this proposed sale for the sliding scale royalty tracts listed in paragraph 4 of this notice.

(a) The royalty rate on production saved, removed, or sold from this lease is subject to consideration for reduction under the same authority that applies to other oil and gas leases on the Outer Continental Shelf (30 CFR 250.2(e)). The Director, Geological Survey, may grant a reduction for only 1 year at a time. Reduction of royalty rates will not be approved unless production has been underway for 1 year or more.

(b) Although the royalty rate specified in section 6(a), as amended, of this lease or as subsequently modified in accordance with applicable regulations and stipulations is applicable to all production under this lease, not more than 16⅔ percent of the production saved, removed, or sold from the lease area may be taken as royalty in amount, except as provided in section 15(d); the royalty on any portion of the production saved, removed, or sold from the lease in excess of 16⅔ percent may only be taken in value of the production saved, removed, or sold from the lease area.

STIPULATION No. 6

(To be included in any lease resulting from this proposed sale for the following tracts: 65-72 through 65-74, 65-77, 65-78, 65-82 through 65-90, 65-92, 65-93, 65-98 through 65-106, 65-108, 65-112, 65-114, and 65-115.)

Portions of these tracts may contain karst sinkholes. Exploratory drilling operations, emplacement of structures (platforms), or seafloor wellheads for the production or storage of oil or gas will not be allowed on those portions of the tract which contain karst sinkholes until the lessee has demonstrated to the Supervisor's satisfaction that exploratory drilling operations can be safely conducted or structures (platforms), casing, and wellheads can be safely designed and installed at the proposed location.

15. *Information to lessees.* The Department of the Interior will seek the advice of the States of Mississippi, Louisiana, Alabama, and Florida and other Federal agencies, to identify areas of special concern which might require appropriate protective measures for live bottom areas and areas which might contain cultural resources.

If it is determined that live bottom areas might be adversely impacted by the proposed activities, then the Supervisor, in consultation with the Regional Director, Fish and Wildlife Service (FWS), the Manager, and the States, will require the lessee to undertake any measures deemed economically, environmentally, and technologically feasible to protect live bottom areas.

In September 1978, the OCS Lands Act Amendments of 1978, hereinafter referred to as the 1978 Amendments, were enacted. Some sections of current regulations applicable to OCS leasing operations are inconsistent with this new legislation, and the legislation requires the issuance of some new regulations. The inconsistencies will be corrected by rulemakings and the new regulations will be issued as soon as possible. Nevertheless, bidders are notified that provisions of the new OCS Lands Act Amendments shall apply to all leases offered at this lease sale and shall supersede all inconsistent provisions in current regulations applicable to OCS leasing operations.

Some of the tracts offered for lease may fall in areas which may be included in fairways, precautionary zones, or traffic separation schemes. Corps of Engineers permits are required for construction of any artificial islands and all installations and other devices permanently or temporarily attached to the seabed on the Outer Continental Shelf in accordance with section 4(f) of the Outer Continental Shelf Lands Act of 1953, as modified by the 1978 Amendments.

In applying safety, environmental, and conservation laws and regulations, the Supervisor, in accordance with Sec. 21(b) of the OCS Lands Act Amendments of 1978, will require the use of the best available and safest technologies which are determined to be economically feasible. To the extent practicable, the Supervisor will consult with the relevant Federal agencies and the affected State(s) in the execution of these responsibilities.

Bidders are advised that the Departments of the Interior and Transportation have entered into a Memorandum of Understanding dated May 6, 1976, concerning the design, installation, operation, and maintenance of offshore pipelines. Bidders should consult both Departments for regulations applicable to offshore pipelines.

Bidders are also advised that in accordance with Sec. 16 of each lease offered at this sale, the lessor may require a lessee to operate under a unit, pooling, or drilling agreement and that the lessor will give particular consideration to requiring unitization in instances where one or more reservoirs underlie two or more leases with either a different royalty rate or a royalty rate based on a sliding scale.

16. *OCS orders.* Operations on all leases resulting from this sale will be conducted in accordance with the provisions of all Gulf of Mexico OCS orders, as of their effective date, and any other applicable OCS order as it becomes effective.

17. *Suggested bid form.* It is suggested that bidders submit their bids to the Manager, New Orleans Outer Continental Shelf Office, in the following form:

OIL AND GAS BID

The following bid is submitted for an oil and gas lease on the tract of the Outer Continental Shelf specified below:

Tract No.	Total amount per acre bid	Amount of cash bonus submitted with bid
.....	.....	.....

Proportionate Interest of Company(s) Submitting Bid

Qualification No ....
Company

Percent interest ....
Address

.....
Signature
(Please type signer's name under signature.)

18. *Required joint bidders statement.* In the case of joint bids, each joint bidder is required to execute a joint bidder's statement before notary public and submit it with his bid. A suggested form for this statement is shown below.

JOINT BIDDER'S STATEMENT

I hereby certify that ——— (entity submitting bid) is eligible under 43 CFR 3302 to bid jointly with the other parties submitting this bid.

Signature ———

(Please type signer's name under signature.)

Sworn to and subscribed before me this —— day of ———19—.

Notary Public ———
State of ———
County of ———

Dated: September 22, 1978.

ARNOLD E. PETTY,
Acting Associate Director,
Bureau of Land Management.

Approved: September 22, 1978.

JAMES A. JOSEPH,
Acting Secretary
of the Interior.

[FR Doc. 78-27234 Filed 9-28-78 8:45 am]

[4310-09]

Bureau of Reclamation

CASCADE RESERVOIR, BOISE PROJECT, VALLEY COUNTY, IDAHO

Public Notice of the Closing of Portions of Areas Previously Open for Off-Road Vehicle Use at Cascade Reservoir, Boise Project, Valley County, Idaho

In accordance with authorities and requirements of Executive Orders 11644 and 11989, the provisions of title 43, part 420, the off-road vehicle (ORV) use at Cascade Reservoir in the area from Poison Creek in the N½ of section 5 T. 15 N., R. 3 E. through sections 32 and 29 T. 16 N., R. 3 E. to the U.S. Forest Service boundary is hereby terminated. This area was part of an area declared as open to ORV use by public notice 42 FR 15670 published on March 23, 1977, and has since been developed as a public recreation area and is now incompatible with ORV use. This change will become effective 30 days following publication in the FEDERAL REGISTER. This change has been incorporated into the proposal and map which are on file and available for inspection at:

Bureau of Reclamation, Central Snake Project Office, 214 Broadway Avenue, Boise, Idaho 83702.
Reservoir Superintendent, Cascade Dam, Cascade, Idaho 83611.
Valley County Courthouse, County Clerk's Office, Cascade, Idaho 83611.
Cascade City Hall, City Clerk's Office, Cascade, Idaho 83611.
Donnelly City Hall, Donnelly, Idaho 83615.

FOR FURTHER INFORMATION CONTACT:

Mr. Mike Misner, Chief, Recreation Branch, Pacific Northwest Region, Bureau of Reclamation, Federal Building, 550 West Fort Street, Boise, Idaho 83724, telephone area code 208-384-1177.

Dated: September 25, 1978.

R. KEITH HIGGINSON,
Commissioner of Reclamation.

[FR Doc. 78-27441 Filed 9-28-78; 8:45 am]

[4310-70]

National Park Service

CUYAHOGA VALLEY NATIONAL RECREATION AREA ADVISORY COMMISSION

Meeting

Notice is hereby given, in accordance with the Federal Advisory Committee Act, that a meeting of the Cuyahoga Valley National Recreation Area Advisory Commission will be held beginning at 7:30 p.m., e.d.t., on Thursday, October 26, and continuing until approximately 12 noon, e.d.t., Friday, October 27, 1978, at Mohican State Park, located in Ashland County, southwest of Loudenville, Ohio, reached from either State Route 95 or State Route 97.

The Commission was established by Pub. L. 93-555 to meet and consult with the Secretary of the Interior on matters relating to the development of the Cuyahoga Valley National Recreation Area and with respect to carrying out the provisions of the public law.

The members of the Commission are as follows:

Mrs. Robert G. Warren (Chairman)
Mr. Courtney Burton
Mr. Norman A. Godwin
Mr. Donald W. Haskett
Mr. Robert L. Hunker
Mr. James S. Jackson
Mr. Melvin J. Rebholz
Mr. Roger L. Rossi
Mrs. George N. Seltzer
Mrs. Robbie Stillman
Mr. Barry K. Sugden
Mr. Robert W. Teater
Mr. William O. Walker

The meeting will be held in two segments in the meeting room of the Lodge at Mohican State Park. On Thursday, October 26, it will begin at 7:30 p.m., e.d.t., and on Friday, October 27, it will begin at 9 a.m., e.d.t.

Matters to be discussed at this meeting include:

1. Report on park operations.

2. Report by committee on proposed historic easements.
3. Scope of transportation study.

The meeting will be open to the public. Interested persons may submit written statements. Such statements should be submitted to the official listed below prior to the meeting.

Further information concerning this meeting may be obtained from William C. Birdsell, Superintendent, Cuyahoga Valley National Recreation Area, P.O. Box 158, Peninsula, Ohio 44264, telephone 216-653-3313. Minutes of the meeting will be available for public inspection 4 weeks after the meeting at the office of Cuyahoga Valley National Recreation Area, located at 501 West Streetsboro Road, State Route 303, 2 miles east of Peninsula, Ohio.

Dated: September 21, 1978.

JAMES L. RYAN,
Acting Regional Director, Midwest Region.

[FR Doc. 78-27417 Filed 9-27-78; 8:45 am]

[4310-70]

[Order No. 5]

ADMINISTRATIVE ASSISTANT, ET AL., HOPEWELL VILLAGE NATIONAL HISTORIC SITE

Delegation of Authority Regarding Execution of Contracts and Purchase Orders

SECTION 1. Administrative Assistant. The Administrative Assistant, Hopewell Village National Historic Site, may execute, approve, and administer contracts not in excess of $50,000 for supplies and equipment or services, in conformity with applicable regulations and statutory authority and subject to the availability of appropriated funds.

SEC. 2. This order supersedes Hopewell Village National Historic Site Order No. 4, dated June 2, 1977, and published in 42 FR 22642 on August 8, 1977.

Dated: September 12, 1978.

ELIZABETH E. DISRUDE,
Superintendent.

[FR Doc. 78-27418 Filed 9-27-78; 8:45 am]

[4310-70]

REVISED MANAGEMENT POLICY ON HOSTELS

The National Park Service has revised and expanded its policy on hostels to encourage the provision of hostels in areas of the National Park System, where appropriate. Copies of the new policy may be obtained after September 30 by writing the nearest regional office:

Mid-Atlantic Regional Office, National Park Service, 143 South 3d St., Philadelphia, Pa. 19106.
Midwest Regional Office, National Park Service, 1709 Jackson St., Omaha, Nebr. 68102.
North Atlantic Regional Office, National Park Service, 15 State St., Boston, Mass. 02109.
Pacific Northwest Regional Office, National Park Service, 601 4th and Pike Bldg., Seattle, Wash. 98101.
Rocky Mountain Regional Office, National Park Service, 655 Parfet St., P.O. Box 25287, Denver, Colo. 80225.
Southeast Regional Office, National Park Service, 1895 Phoenix Blvd., Atlanta, Ga. 30349.
National Capital Region, National Park Service, 1100 Ohio Drive, SW., Washington, D.C. 20242.
Western Regional Office, National Park Service, 450 Golden Gate Ave., Box 36063, San Francisco, Calif. 94102.
Southwest Regional Office, National Park Service, P.O. Box 728, Santa Fe, N. Mex. 87501.

Dated: September 22, 1978.

WILLIAM J. WHALEN,
Director, National Park Service.

[FR Doc. 78-27416 Filed 9-28-78; 8:45 am]

[7020-02]

UNITED STATES INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-36]

CERTAIN PLASTIC FASTENER ASSEMBLIES

Suspension of Investigation

Notice is hereby given that the United States International Trade Commission on September 22, 1978, affirmed the presiding officer's recommendation of August 22, 1978, and ordered, pursuant to 19 U.S.C. 1337(b)(1), the suspension of Commission investigation No. 337-TA-36 of certain plastic fastener assemblies, effective upon publication in the FEDERAL REGISTER. This suspension will continue until such time that certain physical exhibits in the custody of the U.S. District Court for the Southern District of New York, which have been received in evidence as physical exhibits in connection with the case pending therein, *Dennison Mfg. Co.* v. *Ben Clements & Sons, Inc.*, 75 Civ. 979 (CES), will become available to the presiding officer for a period of not less than five (5) months. The suspension was requested by a joint motion of the complainant, Dennison Manufacturing Co., and respondent, Ben Clements & Sons, Inc., on August 11, 1978 (motion docket No. 36-24). In addition, the Commission affirmed the presiding officer's recommendation of August 27, 1978, to grant a 30-day extension for completion of the hearing once the suspension is lifted and the investigation resumed (19 CFR 210.41(e)(1)).

Notice of institution of the investigation was published in the FEDERAL REGISTER on August 11, 1977 (42 FR 40786).

By order of the Commission.

Issued: September 26, 1978.

KENNETH R. MASON,
Secretary.

[FR Doc. 78-27614 Filed 9-28-78; 8:45 am]

[7020-02]

[Investigation No. 337-TA-36]

CERTAIN PLASTIC FASTENER ASSEMBLIES

Commission Order and Memorandum

PROCEDURAL BACKGROUND

On August 15, 1978, a joint motion for the termination of 11 party respondents[1] to the subject investigation was filed by the complainant, Dennison Manufacturing Co., the Commission investigative attorney, and a party respondent, Ben Clements & Sons. None of the other party respondents expressed objection to the motion for termination. The presiding officer, acting in conformity with §§ 210.51 (a) and (c) and 210.53 of the Commission's rules of practice and procedure,[2] concluded that no violation of section 337 of the Tariff Act of 1930, as amended,[3] exists with respect to the 11 respondents and, by order of August 22, 1978,[4] recommended that the 11 companies be terminated as party-respondents.

DETERMINATION AND ORDER

Having considered the motion to terminate and the reasons set forth therein, the Commission determines that Lozio et Figli S.A.S.; Tokyo Style Ltd.; Teknotex; Yoo Joh & Co.; Osabe Marking System, Dae Won Kang Up Co. Ltd.; Dong Shin Pharmaceutical Co. Ltd.; Yoo & Co.; Tong Shin Co. Ltd.; Marketing Resources Co.; and Han Sung Trading Co. are not currently in violation of section 337.

Accordingly, the Commission grants motion 36-25 and orders that the above-named companies be, and hereby are, terminated as party respondents to the instant investigation.

OPINION

The joint motion of August 15, 1978, was accompanied by a statement that

[1] Those 11 party respondents are Lozio et Figli S.A.S.; Tokyo Style Ltd.; Teknotex; Yoo Joh & Co.; Okabe Marking System; Dae Won Kang Up Co. Ltd.; Dong Shin Pharmaceutical Co. Ltd.; Yoo & Co.; Tong Shin Co. Ltd.; Marketing Resources Co.; and Han Sung Trading Co.

[2] 19 CFR 210.51 (a) and (c) and 210.53.

[3] 19 U.S.C. 1337.

[4] Recommended determination to dismiss all respondents named by the Commission in the notice of this investigation except for the respondent Ben Clements & Sons, Inc., filed Aug. 22, 1978.

the Commission should terminate its investigation as to the 11 respondents because none of the 11 is now engaged in exporting or importing into the United States products which could be affected by a remedy in this investigation. In view of this fact and because the complainant, the Commission investigative attorney, and the only active respondent all support the termination of the 11 companies as party respondents, the Commission has determined that those 11 companies are not in violation of section 337 and has granted the joint motion.

By order of the Commission.

Issued: September 26, 1978.

KENNETH R. MASON,
Secretary.

[FR Doc. 78-27615 Filed 9-28-78; 8:45]

[7020-02]

[AA1921-184]

PORTLAND HYDRAULIC CEMENT FROM CANADA

Determination of No Injury or Likelihood Thereof

On June 23, 1978, the U.S. International Trade Commission received advice from the Department of the Treasury that portland hydraulic cement from Canada is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)). Accordingly, on June 29, 1978, the Commission instituted investigation No. AA1921-184 under section 201(a) of said act to determine whether an industry in the United States is being, or is likely to be injured, or is prevented from being established, by reason of the importation of such merchandise into the United States. For purposes of treasury's determination, the term "portland hydraulic cement" refers to portland hydraulic cement, other than white nonstaining.

Notices of the institution of the investigation and of the public hearing held in connection therewith were published in the FEDERAL REGISTER on July 6, 1978 (43 FR 29192). On July 26-28, 1978, a hearing was held in Washington, D.C. at which all persons who requested the opportunity were permitted to appear by counsel or in person.

In arriving at its determination, the Commission gave due consideration to all written submissions from interested persons and information adduced at the hearing as well as information obtained by the Commission's staff from questionnaires, personal interviews, and other sources.

On the basis of information developed in investigation No. AA1921-184, the Commission has determined (Commissioner George M. Moore dissenting and Chairman Joseph O. Parker and Commissioner Daniel Minchew not participating) that an industry in the United States is not being and is not likely to be injured, and is not prevented from being established by reason of the importation of portland hydraulic cement from Canada that is being, or is likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended. Commissioner George M. Moore determined that an industry in the United States is being injured by reason of the importation of portland hydraulic cement into the United States from Canada that is being sold at less than fair value within the meaning of the Antidumping Act, 1921, as amended.

STATEMENT OF REASONS OF COMMISSIONER CATHERINE BEDELL [1]

In order for a Commissioner to make an affirmative determination in an investigation under the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), it is necessary to find that an industry in the United States is being or is likely to be injured, or is prevented from being estalished,[2] and the injury or likelihood thereof must be by reason of imports at less than fair value (LTFV).

DETERMINATION

On the basis of information obtained in this investigation, I determine that an industry in the United States is not being injured and is not likely to be injured by reason of the importation of portland hydraulic cement from Canada, which the Department of the Treasury (Treasury) has determined is being, or is likely to be, sold at LTFV.

THE IMPORTED ARTICLE AND THE DOMESTIC INDUSTRY

Portland hydraulic cement other than white nonstaining, the subject of this investigation, is a major building material and is used in road and building construction. A comparable class of merchandise is produced in the United States by 57 companies at 163 plants. I consider the relevant industry in this investigation to consist of those facilities in the United States devoted to the production of portland hydraulic cement but where the possible impact of LTFV sales is on the producers serving the northeast regional market.[3]

LTFV SALES

The Treasury investigation covered sales during the period April 1, 1977, to August 31, 1977. The investigation was limited to four companies who together accounted for about 84 percent of all sales of portland hydraulic cement from Canada to the United States. Comparisons were made on about 72 percent of the portland hydraulic cement sold for export to the United States by the four producers investigated. Treasury found LTFV margins on the following percentages of sales by these manufacturers: 100 percent of the sales by Miron Co., Ltd.; 51 percent of sales by Lake Ontario Cement, Ltd.; 78 percent of the sales by Canada Cement Lafarge, Ltd.; and 99 percent of the sales by St. Lawrence Cement Co. Treasury found the weighted average of the four Canadian producers to be 50.1 percent.

INDUSTRY "REGIONAL" IN CHARACTER

The statue requires the Commission to make its determination based upon "an industry in the United States." It is recognized, however, that an industry may be considered "regional" in character particularly where: (1) Donestic producers of an article are located regionally and serve a particular regional market predominantly or exclusively, and (2) the LTFV imports are concentrated primarily in the regional market.[4] In this case, both criteria are met as respects the northeast market. first, transportation costs tend to prohibit shipments of portland hydraulic cement for sale at competitive prices more than 300 mile from the producing plant. Second, LTFV sales were reported by Treasury only as to those shipment to this market, over 80 percent of imports from Canada being to this market; price comparisons also were made by Treasury only on the four firms that shipped the major part of their exports to the northeast market.

The cement industry singularly has been one of those with respect to which it has been well-recognized that there are separate geographical marketing areas. In a 1978 publication of the Portland Cement Association,[5] it is stated in part:

> Cement manufacture is a regional industry primarily because of the low value-to-weight ratio of the product. Cement plants tend to be located 150 to 200 miles of their principal markets. Beyond that distance, overland transportation costs become excessive in relation to the value of the product.

The regional character of the industry tends to be diluted to some extent

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[1] Commissioner Italo H. Ablondi concurs in the result.

[2] Prevention of the establishment of an industry is not an issue in this investigation and will not be discussed further.

[3] The northeast market includes the States of New York, Maine, New Hampshire, Vermont, Massachusetts, Connecticut, and Rhode Island.

[4] U.S. Senate, report of the committee on finance to accompany H.R. 10710, trade Act of 1974, S. Rept. No. 93-1298 (93d Cong., 2d Sess.) 1974 at pp. 180-81.

[5] The U.S. Cement Industry an Economic Report, p. 6.

by shipments made much greater distances than 200 or 300 miles in circumstances where prices are favorable and demand is great or water transportation facilities are available to the producer. Nevertheless, the evidence in this case is generally supportive of the regional market concept of the cement industry at this time, and most careful consideration has been given to this matter in this determination. The regional market concept was recognized by the Commission in previous cement antidumping determinations.

INJURY TO U.S. INDUSTRY NOT CAUSED BY LTFV SALES

Whatever injury the domestic industry is suffering, it is not by reason of imports sold at LTFV.

DOMESTIC INDUSTRY—CONDITIONS AS A WHOLE

The U.S. cement industry as a whole is prospering throughout the United States with the exception of certain geographical areas such as the northeast market. Production, prices, plant utilization, and employment are increasing; wages are high in comparison to other industries. There are severe shortages in various parts of the United States and all economic predictions are that the shortage will become more acute in the near future. The indications are that shortages are even being felt in some of the geographical market areas in which economic conditions relating to the use of cement are depressed.

Employment in the hydraulic cement industry, labor productivity, and average earnings of production and related workers all increased markedly during the 1975–77 period. The average earnings increased 25 percent during this period compared with an 11 percent increase for construction workers and 16 percent for all manufacturing workers.

Plant utilization increased nationally from 62.9 percent to 75 percent during the 1975–77 period based on total annual grinding capacity. In 1977, the industry had increased the grinding output to a total of 76 million short tons; the total grinding capacity of the U.S. plants is 104 million short tons.

NORTHEAST MARKET CONDITIONS

Economic Recession

U.S. consumption in the northeast market decreased annually during the 1975–77 period from 4.8 million tons to 4.5 million tons. Consumption in the January–March 1978 period in the northeast market increased 2 percent over the same period in 1977, an indication that economy recovery is beginning in this market. Concrete and concrete products are essential in practically all construction and demand for cement as a raw material for concrete is heavily dependent on construction activity. All indications are that much of the United States recovered much more quickly than the northeast area and that there have been and are severe shortages of cement in many other areas. In fact, shortages are beginning to appear presently in some local areas of the northeast market.

Severe Competition in the Northeast Market

The large number of domestic facilities selling in the northeast market where consumption was decreasing resulted in severe competition, especially since some of the facilities were situated so their sales were restricted to this market while others were situated to enable some sales to adjacent markets. There was no substantial evidence that the Canadians were the leaders to decrease the price of cement. Two instances were found where a lower price for the Canadian product was considered as one of the factors in the decision to purchase. All other indications were that the prices in some city areas in the northeast market were lower for the domestic product and in other city areas the Canadian product was lower-priced. There did not appear to be any indication of a predominance of one or the other type of circumstance. There were, however, several incidents of domestic producers cutting the price and holding the line on such price when increases were announced either by other domestic companies or Canadian importers. By and large, the sellers of Canadian cement were within the range of prices of a local area.

Many of the purchasers of cement in the northeast market have been using Canadian cement for many years, others stated that the shortage in 1973 resulted in the purchase of the Canadian product as the prime or alternate source of supply of cement. Many purchasers asserted better service and delivery of the Canadian product.

"White" Sale of Inventory of Closed Plant

Subsequent to the announcement of the closing of the Universal Atlas plant at Hudson, N.Y., in september 1976, there was an inventory disposal sale at discount prices which resulted in fairly widespread price decreases. The majority of the cement customers contacted with respect to possible lost sales by the domestic industry to Canadian cement contended that the domestic industry overreacted to happenings and reduced prices prematurely. The inventory disposal sale resulted in fairly widespread price decreases.

No Tangible Evidence of Price Suppression

It has not been established that the presence of the LTFV cement in the northeast market caused a suppression of price. Although New York City in this case has been considered to be a part of the northeast market, little or no Canadian cement actually entered into the city's market. Prices, nevertheless, were less during the 1975–1977 period than in most areas of the United States. Again, in Philadelphia, which was not considered to be a part of the northeast market, and where there was little or no Canadian cement in the market, prices were more depressed than in the northeast market.

Increased Fuel and Environmental Costs

Although separate figures are not readily available as to fuel and environmental costs in the northeast area, the cement industry as a whole has been particularly adversely affected by increasing fuel and power prices. Energy costs represent about 40 percent of the cost of finished cement.

The domestic cement industry has estimated that $500 million was spent by cement producers during the period 1971–77 in order to comply with air, water-control and land-use regulations.

Employment

One of the most important factors in considering whether there is injury to a domestic industry is what the employment situation is in the industry. Counsel for the Glen Falls Division of the Flintkote Co., which initially presented information to the Treasury Department resulting in the antidumping investigation, remarked in his opening statement at the Commission hearing that the Commission was not going to find that employees were laid off,[6] and our investigation provided no statistics to support a finding of lessened empoyment in the northeast market.

Utilization of Production Facilities Increased

Capacity utilization in the northeast market from the period 1975–77 increased from 62 percent to 77 percent, the largest percentage increase of the various geographical markets for the entire U.S. cement industry. One of the main reasons for the increased utilization in the northeast area was that there were three cement plant closings, apparently old facilities which were not in compliance with environmental regulations.

FINDINGS OF NO PRESENT INJURY

Due to the particular circumstances in the industry as a whole in the

[6]Transcript of the hearing, p. 12.

United States, there is no possibility of finding injury by reason of sales at LTFV if consideration is given to the industry and its national market. It is also most evident from the facts and circumstances that even taking cognizance of a geographical market area, referred to as the northeast market, there is no present injury.

NO LIKELIHOOD OF INJURY BY REASON OF LTFV SALES

I also determine that there is no likelihood of injury to the domestic industry producing portland hydraulic cement that sells a substantial part of its output in the northeast market. Increased apparent consumption and recent price increase announcements are an indication that demand for cement is on the upswing even in the northeast market. Indeed, much evidence has been recently submitted indicating that the cement shortage already evident in many other areas of the country is beginning to appear in the northeast. The four Canadian companies found by Treasury to be making LTFV sales, and other Canadian producers, are receiving purchase orders from many areas of the United States and are finding it difficult to keep up with the growing demand for their output.

STATEMENT OF REASONS OF VICE CHAIRMAN BILL ALBERGER

In order for a Commissioner to make an affirmative determination in an investigation under the Antidumping Act, 1921, as amended (19 U.S.C. 160(a)), it is necessary to find that an industry in the United States is being or is likely to be injured, or is prevented from being established,[7] and the injury or likelihood thereof must be by reason of imports at less than fair value (LTFV).

DETERMINATION

On the basis of information obtained in this investigation, I determine that an industry in the United States is not being injured and is not likely to be injured by reason of the importation of portland hydraulic cement from Canada, which the Department of the Treasury (Treasury) has determined is being, or is likely to be, sold at LTFV.

THE IMPORTED ARTICLE AND THE DOMESTIC INDUSTRY

Portland hydraulic cement other than white nonstaining, the subject of this investigation, is a major building material and is used in road and building construction. I consider the relevant industry in this investigation to be those facilities in the United States devoted to the production of portland hydraulic cement. In 1977, portland hydraulic cement was produced by 57 companies in 163 plants.

LTFV SALES

The Treasury investigation covered sales during the period April 1, 1977, to August 31, 1977. The investigation was limited to four companies who together accounted for about 84 percent of all sales of portland hydraulic cement from Canada to the United States. Comparisons were made on about 72 percent of the portland hydraulic cement sold for export to the United States by the four producers investigated. Treasury found LTFV margins on the following percentages of sales by these manufacturers: 100 percent of the sales by Miron Co., Ltd.; 51 percent of sales by Lake Ontario Cement, Ltd.; 78 percent of the sales by Canada Cement Lafarge, Ltd.; and 99 percent of the sales by St. Lawrence Cement Co. Treasury found the weighted average margin of the four Canadian producers to be 50.1 percent.

THE ISSUE OF A NATIONAL OR REGIONAL INDUSTRY

It was urged by the petitioners and other domestic industry representatives that the Commission look at injury to a regional market, namely the northeast.

The statute requires the Commission to make its determination based upon "an industry in the United States". The industry may be considered "regional" in character, particularly where: (1) Domestic producers of an article are located in and serve a particular regional market predominantly or exclusively, and (2) the LTFV imports are concentrated primarily in the regional market.[8] In this investigation, both criteria are met.

The Senate Finance Committee in discussion of the Trade Act agreed with the principle of geographic segmentation in antidumping cases. However, the Committee further agreed that there might be instances where application of the principle might be inappropriate—

> • • • , the Committee believes that each case may be unique and does not wish to impose inflexible rules as to whether injury, to regional producers always constitutes injury to an industry.[9]

I believe this case is one of those "unique" instances where application of the regional concept is inappropriate. My belief is based on the major impact a dumping finding would have on the entire U.S. market where shortages clearly exist. Evidence presented to the Commission attests to the current shortage of portland hydraulic cement, particularly in the Western half of the United States, and to the distinct indication that such shortages are growing throughout the country. High prices in areas of short supply are encouraging transportation over much longer distances than are normally economical in this industry. I could well have found the regional industry is not being injured and is not likely to be injured. However, the legislative history makes it clear that the Commission must analyze the appropriateness of regional injury on a case by case basis. While the criteria for such analysis have been met here, I believe that, due to the reasons stated, consideration on national basis is more apropriate in this investigation.

THE QUESTION OF INJURY OR LIKELIHOOD THEREOF BY REASON OF LTFV SALES

Imports and market share.—Imports from Canada from 1975 through 1977 increased by 254 thousand tons, an increase of $14 million in value. Canada's share of total U.S. imports increased from 45 to 57 percent in the same time frame. From 1975 through June, 1978, imports from Canada have represented 1.6 percent of apparent U.S. consumption.

Capacity utilization.—From 1975 through 1977, U.S. producers' capacity utilization increased by slightly more than 19 percent.

U.S. producers' shipments.—Shipments of portland hydraulic cement from 1975 through 1977 increased from 66 million tons to 76 million tons, a value increase of $700 million. This increase in shipments reflects an increase in most types of construction.

Consumption.—U.S. consumption exhibited a steady upward climb in the amount of 9 million tons from 1975 through 1977. There is evidence that consumption will continue to increase in 1978.

Employment.—The average number of production and related workers in the U.S. hydraulic cement industry increased slightly from 1975 through 1977. Average hourly earnings for this group increased by $1.59.

Profits.—Data obtained in Commission questionnaires with regard to financial performance showed that the ratio of net profit to net sales increased from 5.7 percent in 1975 to 11.2 percent in 1977.

Prices.—Prices of both U.S. and Canadian portland hydraulic cement varied from 1975 through June, 1978, but generally moved upward while remaining relatively close to each other.

Lost sales.—In checking allegations of lost sales, the Commission found many U.S. purchasers began purchasing the Canadian product in 1973–74 when domestic producers were unable

[7] Prevention of the establishment of an industry is not an issue in this investigation and will not be discussed further.

[8] U.S. Senate, Report of the Committee of Finance to accompany H.R. 10710, Trade Act of 1974, S. Rept. No. 93-1298 (93d Cong., 2d Sess.) 1977 at pp. 180-181.

[9] Senate Report, supra, at pp. 180-181.

to meet their needs and had continued buying cement from Canada since then. In most instances, the purchase price for both U.S. and Canadian cement was virtually the same.

Summary.—Based on the growth of domestic shipments, capacity utilization, consumption, employment, a reasonable profit picture, stable prices, and little evidence of lost sales due to prices, I conclude the domestic industry producing portland hydraulic cement is not being injured and is not likely to be injured by reason of LTFV imports from Canada.

DISSENTING VIEWS OF COMMISSIONER GEORGE M. MOORE

DETERMINATION

On the basis of information developed during this investigation, which is outlined in the accompanying report, I have determined that an industry in the United States is being injured by reason of the importation of portland hydraulic cement from Canada, which the Department of the Treasury (Treasury) has determined is being, or is likely to be, sold at less than fair value (LTFV).

LTFV SALES

The Treasury investigation covered domestic sales of portland hydraulic cement imports from April 1, 1977 to August 31, 1977. Treasury limited its investigation to four Canadian companies. For all four of these companies all U.S. sales were found at LTFV. These companies accounted for about 84 percent of all sales of imports of portland hydraulic cement to the United States from Canada and for nearly 100 percent of Canadian imports of such cement into the Northeast market area.[10] Thus Treasury found that all sales that occurred in the Northeast market were at LTFV. The four Canadian manufacturers were: Miron Co., Ltd.; Lake Ontario Cement, Ltd.; Canada Cement Lafarge, Ltd.; and St. Lawrence Cement Co. Treasury found that the weighted average LTFV margins of the four Canadian producers were over 50 percent.

THE U.S. INDUSTRY INJURED BY LTFV IMPORTS

The four Canadian producers included in Treasury's investigation shipped nearly all of their exports into the Northeast market during the period of Treasury's investigation. Therefore, in measuring the impact of the LTFV sales I have determined that the affected domestic market is in the northeast section of the United States.

[10]The northeast market includes the States of New York, Maine, New Hampshire, Vermont, Massachusetts, Connecticut, and Rhode Island.

The Antidumping Act of 1921, as amended, requires the Commission to make its determination based upon injury to an industry in the United States. However, the legislative intent of the Act shows clearly that the Commission has the discretion, upon the discovery of appropriate economic facts and circumstances, to make its injury determination based on geographical regional segments or market areas within the United States.

The legislative history of the Trade Act of 1974 provides explicit support for the Commission's treatment of "regional markets" in antidumping investigations:

> A hybrid question relating to injury and industry arises when domestic producers of an article are located regionally and serve regional markets predominately or exclusively and the less-than-fair-value imports are concentrated in a regional market with resultant injury to the regional domestic producers. A number of cases have involved this consideration, and where the evidence showed injury to the regional producers, the Commission has held the injury to a part of the domestic industry to be injury to the whole domestic industry. The Committee agrees with the geographic segmentation principle in antidumping cases. (S. Rept. No. 93-1298, 93d Cong., 2d Sess. 180-181 (1974).)

Economic conditions in the northeast United States require that shipments of portland hydraulic cement to that geographical section must be produced in or near that area. Since LTFV sales from Canada were found only in the northeast market, it is clear that this market area is the only one in which there is competition between LTFV imports and the domestically produced cement.

INJURY BY REASON OF LTFV SALES

Portland hydraulic cement imports from Canada into the northeast market increased in 1977 over 1975, and also increased in the January-March 1978 period as compared to the January-March 1977 period. These increases resulted in a penetration into the domestic market by LTFV Canadian imports of 23.2 percent in 1977 as compared to 17.3 percent in 1975. This penetration into the northeast increased to 31.7 percent in the first quarter of 1978.

Idle capacity.—During the period of rising LTFV imports idle capacity of the domestic plants that ship to the northeast market remained at all times over 23 percent.

U.S. producers' shipments.—Annual shipments by U.S. producers into the northeast market declined from 3.7 million tons in 1975 to 3.3 million tons in 1977. This decline coincided with the increase in LTFV imports and continued into the first 3 months of 1978.

Net losses of U.S. industry.—The domestic plants supplying the northeast market reported operating losses throughout the 1975–June 1978 period. The ratio of net loss to net sales ranged from a low of 5.5 percent in 1976 to a high of 21.9 percent during the first half of 1978. In 1977, losses were almost 16 percent of net sales. Evidence developed by the Commission indicates that the domestic producers in the Northeast are not able to operate at even a reasonable level of profit, because they are forced to compete with LTFV sales of Canadian imports.

Suppressed prices and lost sales.—Delivered prices for portland hydraulic cement in the northeast market during the period 1975–78 were suppressed by sales of LTFV imports, and, after correction for transportation costs, they were appreciably lower than in other areas of the United States. For example, in the last quarter of 1977, domestic prices of such cement were $44.72 per ton in Seattle, Wash., and $50.15 in Grand Forks, N.D. In the Northeast United States, however, prices ranged from $31.30 per ton in Albany, N.Y., to $37.84 in Syracuse, N.Y. while, at the same time, LTFV import prices remained below or about the same as domestic prices. This suppression in the northeast market caused by LTFV imports prevented the domestic producers from recovering costs or earning an adequate return on their investments.

In several cases, the Commission found evidence that customers of portland hydraulic cement changed from domestic to Canadian suppliers because of the lower price of the Canadian cement.

CONCLUSION

In my opinion, the injury to the domestic industry in the northeast market area caused by LTFV sales is more than trivial or inconsequential. This is all that is required for an affirmative determination by the Commission under the Antidumping Act of 1921 as amended. Based upon the above considerations, I have determined that the U.S. industry producing portland hydraulic cement is being injured by reason of the importation of such cement from Canada which is being sold at LTFV in the northeast U.S. market area.

Issued: September 26, 1978.

By order of the Commission:

KENNETH R. MASON,
Secretary.

[FR Doc. 27616 Filed 9-28-78; 8:45 am]

[4410-09]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

CONTROLLED SUBSTANCES IN SCHEDULES I AND II

Proposed 1978 Revised Aggregate Production Quota and Establishment of an Interim Aggregate Production Quota—Thebaine For Conversion

Section 306 of the Controlled Substances Act of 1970 (21 U.S.C. 826) requires the Attorney General to establish aggegate production quotas for all controlled substances in schedules I and II each year. This responsibility has been delegated to the Administrator of the Drug Enforcement Administration pursuant to § 0.100 of title 28 of the Code of Federal Regulations.

On August 11, 1978, a notice of the proposed revised aggregate production quota for 1978 for thebaine for conversion was published in the FEDERAL REGISTER (43 FR 35758). All interested parties were invited to comment on or object to the proposed aggregate production quota on or before September 15, 1978. One comment was received. Mallinckrodt, Inc. of St. Louis, informed DEA that it desired to produce nalbuphine, a non-controlled substance derived from thebaine, in 1978. In order to allow Mallinckrodt to produce nalbuphine in 1978, the aggregate production quota must be further increased above the 1,397,000 grams proposed on August 11, 1978.

To provide for the legitimate needs for this substance in 1978, the Drug Enforcement Administration hereby establishes an interim 1978 aggregate production quota for thebaine for conversion of 1,397,000 grams expressed as anhydrous base. In addition, based upon consideration of the request made by Mallinckrodt, Inc., the Administrator of the Drug Enforcement Administration does hereby propose that the aggregate production quota for thebaine for conversion in 1978 be established at 2,217,000 grams, expressed as anhydrous base.

All interested persons are invited to submit their comments and objections in writing regarding this proposal. Comments and objections should be submitted in quintuplicate to the Administrator, Drug Enforcement Administration, United States Department of Justice, Washington, D.C. 20537, Attention: DEA Federal Register Representative, and must be received by October 30, 1978. If a person believes that one or more issues raised by him warrants a full adversary-type hearing, he should so state and summarize the reasons for this belief.

In the event that comments or objections to this proposal raise one or more issues which the Administrator finds, in his sole discretion, warrants a full adversary-type hearing, the Administrator shall order a public hearing in the FEDERAL REGISTER summarizing the issues to be heard and setting the time for the hearing.

The establishment of the interim aggregate production quota for thebaine for conversion is effective September 29, 1978.

Dated: September 22, 1978.

PETER B. BENSINGER,
Administrator.

[FR Doc. 78-27497 Filed 9-28-78; 8:45 am]

[4410-09]

IMPORTER OF CONTROLLED SUBSTANCES

Registration

By Notice dated July 28, 1978, and published in the FEDERAL REGISTER on August 8, 1978 (43 FR 35123), Research Technology Branch, Division of Research, NIDA, Room 9-42, 5600 Fishers Lane, Rockville, Md. 20857, made application to the Drug Enforcement Administration to be registered as an importer of the basic classes of controlled substances listed below to be imported for research proposes only:

Drug:	*Schedule*
Lysergic acid diethylamide (7315)	I
Marihuana (7360)	I
Tetrahydrocannabinols (7370)	I
Psilocybin (7437)	I
Psilocyn (7438)	I
Buprenorphine (9064)	II

No comments or objections having been received, and, pursuant to section 1008(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and in accordance with title 21, Code of Federal Regulations § 1311.42, the above firm is granted registration as an importer of the basic classes of controlled substances listed above for research purposes only.

Dated: September 21, 1978.

PETER B. BENSINGER,
Administrator,
Drug Enforcement Administration.

[FR Doc. 78-27496 Filed 9-28-78; 8:45 am]

[4510-30]

DEPARTMENT OF LABOR

Employment and Training Administration

EMPLOYMENT TRANSFER AND BUSINESS COMPETITION DETERMINATIONS UNDER THE RURAL DEVELOPMENT ACT

Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 U.S.C. 1924(b), 1932, or 1942(b).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate, or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility. The act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within 2 weeks of publication of this notice to:

Deputy Assistant Secretary for Employment and Training, 601 D Street NW., Washington, D.C. 20213.

Signed at Washington, D.C., this 25th day of September 1978.

ERNEST G. GREEN,
Assistant Secretary for Employment and Training.

APPLICATIONS RECEIVED DURING THE WEEK ENDING SEPTEMBER 22, 1978

Name of Applicant, Location of Enterprise, and Principal Product or Activity

Mercer Mall, Mercer County, W. Va., Shopping mall.
Suwannee Valley Production & Marketing Corp., Lake City, Fla., Processing of dried poultry waste into nitrogenous products.
Holiday Inn., Wisconsin Dells, Wisc., Motel.
Chase Resorts, Inc., Lake Ozark, Mo., Resort and conference hotel.
Bosarge, O'Brien, Wadsworth & Lewis, Frisco, Colo., Motel with restaurant, lounge, and meeting rooms.
Big Boy Restaurants of Alaska, Inc., Fairbanks, Alaska, Fast food restaurant.
Carter Enterprises, Inc., Olive Hill, Ky., Production and sales of moderate-priced prefabricated housing, and lumber and building and building supplies.
Monfort of Kansas, Inc., Oakley, Kans., Beef slaughter and fabrication.
Quality Mushrooms, Inc., Ephraim, Utah, Mushroom plant.
Tag Services, Inc., St. Mary Parish, La., Rental of oilfield drilling equipment and operators.
Showell Farms, Inc., Queen Annes and Caroline, Counties, Md., Integrated poultry facility.
Top Flite Development Corp., Kodak, Tenn., Truck stop-motel, restaurant, and convenience store.
Campbell Manufacturing Co., Walthill, Nebr., Manufacture of field sprayers, agricultural wagons, and plastic tanks.
Hamilton, Inc., Wewahitchka, Fla., Operation of offshore service supply vessels.

[FR Doc. 78-27237 Filed 9-28-78 8:45 am]

[4510-30]

FUNDS UNDER COMPREHENSIVE EMPLOYMENT AND TRAINING ACT (CETA)

Allocation Methodology

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice provides the methodology for the allocation of funds under title VI of the Comprehensive Employment and Training Act in fiscal year 1979. The purpose of this notice is to advise all interested parties of this allocation methodology.

DATE: Comments must be received on or before October 30, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert T. Jones, Director, Office of Community Employment Programs, Room 5402, 601 D Street NW., Washington, D.C. 20213, telephone 202-376-6366.

SUPPLEMENTARY INFORMATION: To assure an equitable distribution of title VI funds in fiscal year 1979 and to provide for the continuation of title VI programs, the Secretary of labor, pursuant to his reallocation authority under section 606 of CETA and his allocation authority under section 603 of CETA shall implement an allocation procedure which would apply to available unspent carry-in funds as of October 1, 1978, and new title VI obligational authority (NOA) for fiscal year 1979. With such a procedure the fiscal year 1979 allocation formula would be applied to the sum of title VI carry-in funds and NOA for fiscal year 1979. Each prime sponsor would then receive the difference between its allotment, computed under this method, and its carry-in funds. Under this method no prime sponsor would receive less total funds (NOA plus carry-in) than it would have received if the allocation formula were applied only to fiscal year 1979 NOA.

This procedure would combine two administrative processes, the reallocation of unspent carry-in funds and the allocation of fiscal year 1979 funds, and thus provide a programmatically efficient means of attaining the program goals without the administrative burdens and time difficulties that an ordinary reallocation of unspent funds may experience. The end result of this method would be the receipt of the same amount of funds as if the carry-in funds were reallocated and prime sponsors received their regular fiscal year 1979 allotments.

Signed this 19th day of September 1978, at Washington, D.C.

ROBERT J. MCCONNON,
Deputy Assistant Secretary.

[FR Doc. 78-27512 Filed 7-28-78; 8:45 am]

[4510-30]

INDIAN AND NATIVE AMERICAN PROGRAMS

Creek Nation of Oklahoma Added as Prime Sponsor Under Section 302 of the Comprehensive Employment and Training Act

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public of the designation of an additional fiscal year 1979 Indian and Native American prime sponsor of employment and training programs funded under the Comprehensive Employment and Training Act (CETA) of 1973, as amended. The Creek Nation of Oklahoma, P.O. Box 1114, Okmulgee, Okla. 74447 is the added prime sponsor.

FOR FURTHER INFORMATION CONTACT:

Herman E. Narcho, Chief, Policy, Program Design, and Administration, Division of Indian and Native American Programs, Office of National Programs, 601 D Street NW., Room 6414, Washington, D.C. 20213, telephone 202-376-7279.

Signed at Washington, D.C., this 7th day of September 1978.

ALEXANDER S. MACNABB,
Director, Division of Indian and Native American Programs, Office of National Programs.

[FR Doc. 78-27517 Filed 9-28-78; 8:45]

[4510-30]

LABOR SURPLUS AREA CLASSIFICATIONS UNDER DEFENSE MANPOWER POLICY NO. 4A AND EXECUTIVE ORDERS 12073 and 10582

Notice of Quarterly List of Labor Surplus Areas

The labor market areas described below have been classified by the Assistant Secretary of Labor for Employment and Training as labor surplus areas for purposes of Defense Manpower Policy No. 4A (DMP-4A) and Excutive Orders 12073 and 10582.

DMP-4A is implemented by regulations of the Federal Preparedness Agency of the General Services Administration at 32A CFR Part 134. Under DMP-4A, firms which agree to perform most of the work in labor surplus areas are given priority in the award and execution of Federal procurement contracts, grants, and agreements. To carry out this policy, DMP-4A assigns to the Secretary of Labor responsibility for classifying labor surplus areas and disseminating this information on a timely basis to Federal departments and agencies.

Executive Order 12073 also requires executive agencies to emphasize procurement set-asides in labor surplus areas. The Secretary of Labor is also responsible under this Order for classifying and designating labor market areas which are labor surplus areas.

Under Executive Order 10582, executive agencies may reject bids or offers of foreign materials in favor of the lowest offer by a domestic supplier, *Provided*, That the domestic supplier undertakes to produce substantially all of the materials in areas of substantial unemployment, as defined by the Secretary of Labor. Areas of substantial unemployment are defined by Department of Labor regulations as labor surplus areas.

The Department's labor surplus area classification procedures are set forth at 20 CFR Part 654. These regulations require that the Assistant Secretary for Employment and Training publish quarterly a list of labor surplus areas together with corresponding geographic descriptions. Accordingly, the following list of labor surplus areas is published for the use of all Federal departments and agencies in directing procurement activity and locating new plants or facilities.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978

Labor surplus area	Geographic description
Alabama:	
Anniston SMSA	Calhoun County.
Camden	Wilcox County.
Carrollton	Pickens County.
Centreville	Bibb County.
Choctaw County	Choctaw County.
Clanton	Chilton County.
Eutaw	Greene County.
Geneva	Geneva County.
Greensboro	Hale County.
Haleyville	Winston County.
Jackson	Clarke County.
Marion	Perry County.
Mobile SMSA	Baldwin and Mobile Counties.
Moulton	Lawrence County.
Ozark	Dale County.
Roanoke	Randolph County.
Russellville	Franklin County.
Scottsboro	Jackson County.
Selma	Dallas County.
Talladega	Talladega County.
Alaska:	
Angoon Divison	Angoon Division.
Barrow-North Slope Division.	Barrow-North Slope Division.
Bethel Division	Bethel Division.
Bristol Bay Borough Division.	Bristol Bay Borough Division.
Bristol Bay Division	Bristol Bay Division.
Cordova-McCarthy Division.	Cordova-McCarthy Division.
Fairbanks Division	Fairbanks Division.
Haines Division	Haines Division.
Juneau Division	Juneau Division.
Kenai-Cook Inlet Division.	Kenai-Cook Inlet Division.
Ketchikan Division	Ketchikan Division.
Kobuk Division	Kobuk Division.
Kodiak Division	Kodiak Division.
Kuskokwim Division	Kuskokwim Division.
Matanuska-Susitna Division.	Matanuska-Susitna Division.
Nome Division	Nome Division.
Outer Ketchikan Division.	Outer Ketchikan Division.
Prince of Wales Division.	Prince of Wales Division.
Seward Division	Seward Division.
Sitka Division	Sitka Division.
Skagway-Yakutat Division.	Skagway-Yakutat Division.
Southeast Fairbanks Division.	Southeast Fairbanks Division.
Upper Yukon Division	Upper Yukon Division.
Valdez-Chitina-Whittier Division.	Valdez-Chitina-Whittier Division.
Wade Hampton Division.	Wade Hampton Division.
Wrangell-Petersburg Division.	Wrangell-Petersburg Division.
Yukon-Koyukuku Division.	Yukon-Koyukuku Division.
Arizona:	
Douglas	Cochise County.
Globe	Gila County.
Kingman	Mohave County.
McNary	Apache County.
Nogales	Santa Cruz County.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Pinal County	Pinal County.
Safford	Graham County.
Winslow	Navajo County.
Yuma	Yuma County.
Arkansas:	
Blytheville	Mississippi County.
Chicot County	Chicot County.
Clinton	Van Buren County.
Conway	Faulkner County.
Des Arc	Prairie County.
Forrest City	St. Francis County.
Fulton County	Fulton County.
Hardy	Sharp County.
Heber Springs	Cleburne County.
Huntsville	Madison County.
Jasper	Newton County.
Marianna	Lee County.
Marshall	Searcy County.
Mena	Polk County.
Mountain View	Stone County.
Newport	Jackson County.
Ozark	Franklin County.
Piggott	Clay County.
Pocahontas	Randolph County.
Rison	Cleveland County.
Russellville	Pope and Yell Counties.
Searcy	White County.
Waldron	Scott County.
Walnut Ridge	Lawrence County.
California:	
Alpine County	Alpine County.
Angels Camp	Calaveras County.
Bakersfield SMSA	Kern County.
Chico-Oroville	Butte County.
Colusa County	Colusa County.
Crescent City	Del Norte County.
El Centro	Imperial County.
Eureka	Humboldt County.
Fresno SMSA	Fresno County.
Grass Valley	Nevada County.
Hanford	King County.
Hollister	San Benito County.
Jackson	Amador County.
Lakeport	Lake County.
Los Angeles-Long Beach SMSA.	Los Angeles County.
Loyalton	Sierra County.
Madera	Madera County.
Mariposa	Mariposa County.
Merced	Merced County.
Mosesto SMSA	Stanislaus County.
Oxnard-Simi Valley-Ventura SMSA.	Ventura County.
Placerville	El Dorado County.
Quincy	Plumas County.
Red Bluff	Tehama County.
Redding	Shasta County.
Sacramento SMSA	Placer, Sacramento, and Yolo Counties.
Salinas-Seaside-Monterey SMSA.	Monterey County.
San Diego SMSA	San Diego County.
Santa Cruz SMSA	Santa Cruz County.
Santa Rosa SMSA	Sonoma County.
Sonora	Tuolumne County.
Stockton SMSA	San Joaquin County.
Susanville	Lassen County.
Ukiah	Mendocino County.
Vallejo-Fairfield-Napa SMSA.	Napa and Solano Counties.
Visalia	Tulure County.
Weaverville	Trinity County.
Willows	Glenn County.
Yreka	Siskiyou County.
Yuba City	Sutter and Yuba Counties.
Colorado:	
Antonio	Conejos County.
Blanca	Costilla County.
Center	Saguache County.
Delta	Delta County.
Eagle	Eagle County.
Garfield County	Garfield County.
Lake County	Lake County.
Moffat County	Moffat County.
Ouray County	Ouray County.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Pagosa Springs	Archuleta County.
Pitkin County	Pitkin County.
Pueblo SMSA	Pueblo County.
Routt County	Routt County.
Telluride	San Miguel County.
Trinidad	Las Animas County.
Walsenburg	Huerfano County.
Connecticut:	
Ansonia	Towns of Ansonia, Oxford, and Seymour.
Bridgeport SMSA	Towns of Bridgeport, Derby, Easton, Fairfield, Milford, Monroe, Shelton, Stratford, and Trumbull.
Waterbury SMSA	Towns of Beacon Falls, Bethlehem, Chesire, Middlebury, Naugatuck, Prospect, Southbury, Thomaston, Waterbury, Watertown, Wolcott, and Woodbury.
Delaware:	
Dover	Kent County.
Wilmington SMSA	New Castle County, Del.; Cecil County, Md.; Salem County, N.J.
Florida:	
Apalachicola	Franklin County.
Bristol	Liberty County.
Brooksville	Hernando County.
Chipley	Washington County.
Fort Pierce	St Lucie County.
Fort Walton Beach	Oklaloosa County.
Dey West	Monroe County.
Lafayette County	Lafayette County.
Lakeland-Winter Haven SMSA.	Polk County.
Leesburg	Lake County.
Melbourne-Titusville-Cocoa SMSA.	Brevard County.
Miami SMSA	Dade County.
Moore Haven	Glades County.
Panama City SMSA	Bay County.
Port St. Joe	Gulf County.
Sebring	Highlands County.
Vero Beach	Indian River County.
Georgia:	
Albany SMSA	Dougherty and Lee Counties.
Atlanta SMSA	Butts, Cherokee, Clayton, Cobb, De Kalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, Rockdale, and Walton Counties.
Augusta SMSA	Columbia and Richmond Counties, Ga.; Aiken County, S.C.
Barroe County	Barrow County.
Blackshear	Pierce County.
Burke County	Burke County.
Camilla	Mitchell County.
Chattooga County	Chattooga County.
Darien	McIntosh County.
Dawsonville	Dawson County.
Jefferson County	Jefferson County.
Macon SMSA	Bibb, Houston, Jones, and Twiggs Counties.
Pearson	Atkinson County.
Roberta	Crawford County.
Rochelle	Wilcox County.
Thompson	McDuffie County.
Hawaii:	
Hilo	Hawaii County.
Idaho:	
Bonners Ferry	Boundary County.
Camas County	Camas County.
Clark County	Clark County.
Coeur Dalene	Kootenai County.
Council	Adams County.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Emmett	Gem County.
Orangeville	Idaho County.
Horseshoe Bend	Boise County.
Ketchum	Blaine County.
Lemhi County	Lemhi County.
McCall	Valley County.
Orofino	Clearwater County.
Sandpoint	Bonner County.
St. Maries	Benewah County.
Illinois:	
Anna	Union County.
Cairo	Alexander and Pulaski Counties.
Canton	Fulton County.
Carbondale-Murphysboror.	Jackson County.
Carmi	Whie County.
Cass County	Cass County.
Centralia	Marion County.
Danville	Vermillion County.
Du Quoin	Perry County.
Fairfield	Wayne County.
Fayette County	Fayette County.
Flora	Clay County.
Galesburg	Knox County.
Golconda	Pope County.
Greenville	Bond County.
Hardin	Calhoun County.
Harrisburg-West Frankfort-Herrin.	Franklin, Johnson, Saline, and Williamson Counties.
Jerseyville	Jersey County.
Kankakee SMSA	Kankakee County.
Litchfield	Montgomery County.
Mason County	Mason County.
McLeansboro	Hamilton County.
Metropolis	Massac County.
Mount Vernon	Jefferson County.
Olney	Richland County.
Rosiclare	Hardin County.
Shawneetown	Gallatin County.
Schuytler County	Schuyler County.
Shelbyville	Shelby County.
Indiana:	
Linton	Greene County.
Loogootee	Martin County.
Madison	Jefferson County.
Marengo	Crawford County.
Paoli	Orange County.
Rising Sun	Ohio County.
Scottsburg	Scott County.
Iowa:	
Centerville	Appanoose County.
Kentucky:	
Beattyville	Lee County.
Benton	Marshall County.
Brownsville	Edmonson County.
Grayson	Carter County.
Jenkins	Letcher County.
Manchester	Clay County.
McKee	Jackson County.
Owenton	Owen County.
Russell Springs	Russel County.
Salyersville	Magoffin County.
Stanford	Lincoln County.
Stanton	Powell County.
Louisiana:	
Alexandria SMSA	Avoyelles, Grant, and Rapides Parishes.
Bastrop	Morehouse Parish.
Bogalusa	Washington Parish.
Hammond	Tangipahoa Parish.
Jennings	Jefferson Davis Parish.
Jonesville	Catahoula Parish.
Lake Charles SMSA	Calcasieu Parish.
Lake Providence	East Carroll Parish.
Leesville	Vernon Parish.
Lutcher	St. James Parish.
Natchitoches	Natchitoches Parish.
New Roads	Pointe Coupee Parish.
Oakdale	Allen Parish.
Oak Grove	West Carroll Parish.
Opelousas	St. Landry Parish.
Plaquemine	Iberville Parish.
Rayville	Richland Parish.
St. Franisville	West Feliciana Parish.
Tallulah	Madison Parish.
Tensas Parish	Tensas Parish.
Vidalia	Concordia Parish.
Ville Platte	Evangeline Parish.
Winnsboro	Franklin Parish.
Maine:	
Belfast	Waldo County.
Boothbay-Harbor	Lincoln County except towns of Dresden and Waldoboro.
Calais-Eastport	Washington County.
Carbou-Presque Isle	Towns or plantations of Ashland, Blaine, Bridgewater, Caribou, Castle Hill, Caswell, Chapman, Connor, E. Plantation, Easton, Fort Fairfield, Garfield, Limestone, Mapleton, Masardis, Mars Hill, Nashville, New Sweden, Oxbow, Perham, Portage Lake, Presque Isle, Stockholm, Wade, Washburn, Westfield, Westmanland, and Woodland in Aroostook County.
Fort Kent	Towns of Eagle Lake, Fort Kent, Frenchville, St. Agatha; plantations of Allagash, New Sinclair, and Wallagrass in Aroostook County.
Greenville	Towns of Elliotsville, Greeneville, Lily Bay, and Shirley; and southern unorganized territory in Piscataquis County.
Lincoln-Howland	Towns of Burlington, Chester, Enfield, Howland, Lee, Lincoln, Lowell, Mattamiscontis, Mattawamkeag, Maxfield, Passadumkeag, Springfield, Winn, and Woodville; Township of Kingman, Whitney, 1 N.D., 2R-8, 2R-9; and 3R-1; and plantations of Carroll, Drew, Grand Falls, Lakeville, Prentiss, Seboeis, and Webster in Penobscot County.
Livermore Falls	Towns of Green, Leeds, Livermore, Livermore Falls, Turner and Webster in Androscoggin County.
Madawaska-Van Buren	Towns of Grand Isle, Madawask and Van Buren; and plantations of Cyr and Hamlin in Aroostook County.
Skowhegan	Somerset County.
Southwest Penobscot	Towns of Bradford, Carmel, Charleston, Corrina, Corinth, Dexter, Dixmont, Etna, Exeter, Garland, Hudson, Kenduskeag, Levant, Newburg, Newport, Plymount, and Stetson in Penobscot County.
Maryland:	
Baltimore SMSA	Anne Arundel, Baltimore, Carroll, Harford, and Howard Counties; and Baltimore City.
Cambridge	Dorchester County.
Centreville	Queen Annes County.
Chestertown	Kent County.
Crisfield	Somerset County.
Cumberland	Allegany County, Md., and Mineral County, W. Va.
Feralsburg	Carline County.
Hagerstown	Washington County.
Oakland	Garrett County.
Pocomoke City	Worcester County.
Prince Frederick	Calvert County.
Salisbury	Wicomico County.
Massachusetts:	
Barnstable	Barnstable County.
Boston SMSA	Suffolk County; cities of Beverly, Lynn, Peabody, and Salem, and towns of Boxford, Danvers, Hamilton, Lynnfield, Manchester, Marblehead, Middleton, Nahant, Saugus, Swampscot, Topsfield, and Wenham in Essex County; cities of Cambridge, Everett, Malden, Medford, Melrose, Newton, Somerville, Waltham, and Woburn, and towns of Acton, Arlington, Ashland, Bedford, Belmont, Boxborough, Burlington, Carlisle, Concord, Framingham, Holliston, Lexington, Lincoln, Natick, North Reading, Reading, Sherborn, Stoneham, Sudbury, Wakefield, Watertown, Wayland, Weston, Wilmington, and Winchester in Middlesex County; Quincy City and towns of Bellingham, Braintree, Brookline, Canton, Cohaseet, Dedham, Dover, Foxborough, Franklin, Holbrook, Medfield, Medway, Morris, Milton, Needham, Norfolk, Norwood, Randolph, Sharon, Stoughton, Walpole, Wellesley, Westwood, Weymouth, and Wrentham in Norfolk County; towns of Abington, Duxbury, Hanover, Hanson, Hingham, Hull, Kingston, Marshfield, Norwell, Pembroke, Rockland, and Scituate in Plymouth County.
Brockton SMSA	Town of Easton in Bristol County; town of Avon in Norfolk County; city of Brockton, towns of Bridgewater, East Bridgewater, Halifax, West Bridgewater, and Whitman in Plymouth County.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Clinton	Towns of Clinton and Lancaster in Worcester County.
Fall River SMSA	Fall River City; and towns of Dighton, Somerset, Swansea, and Westport in Bristol County, Mass.; and towns of Little Compton and Tiverton in Newport County, R.I.
Gloucester	Gloucester City and towns of Essex and Rockport in Essex County.
Lawrence-Haverhill SMSA.	Cities of Lawrence and Haverhill and towns of Amesbury, Andover, Georgetown, Grovelan, Merrimac, Methuen, North Andover, Salisbury, and West Newbury in Essex County, Mass.; towns of Atkinson, Hampstead, Kingston, Newton, Plaistow, Salem, and Windham in Rockingham County, N.H.
New Bedford SMSA	City of New Bedford, and town of Acushnet, Dartmouth, Fairhaven, and Freetown in Bristol County; towns of Lakeville, Marion, Mattapoisett, and Rochester in Plymouth County.
Newburyport	Newburyport City and towns of Ipswich, Newbury, and Rowley in Essex County.
Plymouth	Towns of Carver, Middleborough, Plymouth, Plympton, and Wareham in Plymouth County.
Taunton	Taunton City, and towns of Berkley and Raynham in Bristol County.
Tisbury	Dukes County.
Ware	Town of Ware in Hampshire County; towns of Hardwick, New Braintree, Oakham, and West Brookfield in Worcester County.
Michigan:	
Adrian	Lenawee County.
Alma	Gratiot County.
Alpena	Alpena County.
Bad Axe	Huron County.
Baldwin	Lake County.
Benton Harbor	Berrien County.
Big Rapids	Mecosta County.
Boyne City	Charlevoix County.
Cadillac	Missaukee, Osceola, and Wexford Counties.
Caro	Tuscola County.
Cheboygan	Cheboygan County.
Clare	Clare County.
Detroit SMSA	Lapeer, Livingston, Macomb, Oakland, St. Clair, and Wayne Counties.
East Tawas	Alcona and Iosco Counties.
Elberta	Benzie County.
Escanaba	Delta County.
Flint SMSA	Genesee and Shiawassee Counties.
Fremont	Newaygo County.
Gaylord	Otsego County.
Grayling	Crawford County.
Greenville	Montcalm County.
Hancock	Houghton and Keweenaw Counties.
Hillman	Montmorency County.
Iron River	Iron County.
Ironwood	Gogebic County.
L'anse	Baraga County.
Ludington	Mason County.
Mancelona	Antrim County.
Manistee	Manistee County.
Manistique	Schoolcraft County.
Marquette	Alger and Marquette Counties.
Midland	Gladwin and Midland Counties.
Mio	Oscoda County.
Muskegon-Norton Shores-Muskegon Heights SMSA.	Muskegon and Oceana Counties.
Newberry	Luce County.
Ontonagon	Ontonagon County.
Petoskey	Emmet County.
Rogers City	Presque Isle County.
Roscommon	Roscommon County.
St. Ignace	Mackinac County.
Sandusky	Sanilac County.
Sault Ste. Marie	Chippewa County.
Standish	Arenac County.
Sturgis	St. Joseph County.
Traverse City	Grand Traverse, Kalkaska, and Leelanau Counties.
West Branch	Ogemaw County.
Minnesota:	
Aitkin	Aitkin County.
Bagley	Clearwater County.
Grand Rapids	Itasca County.
Hibbing-Virginia	St. Louis County less Duluth City.
Little Falls	Morrison County.
Mahnomen	Mahnomen County.
Red Lake Falls	Red Lake County.
Roseau	Roseau County.
Warren	Marshall County.
Mississippi:	
Ashland	Benton County.
Bay Springs	Jasper County.
Belzoni	Humphreys County.
Biloxi-Gulfport SMSA.	Hancock, Harrison, and Stone Counties.
Canton	Madison County.
Charleston	Tallahatchie County.
Clarksdale	Coahoma County.
Cleveland	Bolivar County.
Columbia	Marion County.
Corinth	Alcorn County.
De Kalb	Kemper County.
Fayette	Jefferson County.
Greenville	Washington County.
Greenwood	Leflore County.
Grenada	Grenada County.
Hazlehurst	Copiah County.
Holly Springs	Marshall County.
Indianola	Sunflower County.
Iuka	Tishomingo County.
Kosciusko	Attala County.
Leakesville	Greene County.
Lexington	Holmes County.
Louisville	Winston County.
Lucedale	George County.
Macon	Noxubee County.
Marks	Quitman County.
Natchez	Adams County.
Picayune City	Pearl River County.
Prentiss	Jefferson Davis County.
Rolling Fork	Issaquena and Sharkey Counties.
Senatobia	Tate County.
Tunica	Tunica County.
Vicksburg	Warren County.
Waynesboro	Wayne County.
Winona	Montgomery County.
Woodville	Wilkinson County.
Yazoo	Yazoo County.
Missouri:	
Alton	Oregon County.
California	Moniteau County.
Charleston	Mississippi County.
Doniphan	Ripley County.
Eminence	Shannon County.
Greenville	Wayne County.
Houston	Texas County.
Kennett	Dunklin County.
Marble Hill	Bollinger County.
Poplar Bluff	Butler County.
Potosi	Washington County.
Sedalia	Pettis County.
Steelville	Crawford County.
Versailles	Morgan County.
Warrenton	Warren County.
Montana:	
Anaconda	Deer Lodge County.
Boulder	Jefferson County.
Butte	Silver Bow County.
Cut Bank	Glacier County.
Glasgow	Valley County.
Hamilton	Ravalli County.
Hardin	Big Horn County.
Kalispell	Flathead County.
Libby	Lincoln County.
Phillipsburg	Granite County.
Polson	Lake County.
Superior	Mineral County.
Thompson Falls	Sanders County.
Nebraska:	
Pender	Thurston County.
Nevada:	
Carson City	Carson City and Storey County.
New Jersey:	
Atlantic City SMSA	Atlantic County.
Cape May-Ocean City-Wildwood.	Cape May County.
Jersey City SMSA	Hudson County.
Lakewood-Toms River	Ocean County.
Long Branch-Asbury Park SMSA.	Monmouth County.
Newark SMSA	Essex, Morris, Somerset, and Union Counties.
Newton	Sussex County.
Paterson-Clifton-Passaic SMSA.	Passaic County.
Trenton SMSA	Mercer County.
Vineland-Bridgeton-Millville SMSA.	Cumberland County.
New Mexico:	
Deming	Luna County.
Espanola	Rio Arriba County.
Las Vegas	San Miguel County.
Santa Rosa	Guadaloupe County.
Taos	Taos County.
Wagon Mound	Mora County.
New York:	
Auburn	Cayuga County.
Batavia	Genesee County.
Binghamton SMSA	Broome and Tioga Counties, N.Y.; and Susquehanna County, Pa.
Buffalo SMSA	Erie and Niagara Counties.
Catskill	Greene County.
Cobleskill	Schoharie County.
Cortland	Cortland County.
Elmira SMSA	Chemung County.
Glen Falls-Hudson Falls.	Warren and Washington Counties.
Gloversville	Fulton County.
Kingston	Ulster County.
Lowville	Lewis County.
Malone	Franklin County.
Monticello	Sullivan County.
Newburgh-Middletown.	Orange County.
New York SMSA	Bronx, Kings, New York, Putnam, Queens, Richmond, Rockland, and Westchester Counties.
Ogdensbury-Massena	St. Lawrence County.
Olean-Salamanca	Cattaraugus County.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Penn Yan	Yates County.
Perry	Wyoming County.
Plattsburg	Clinton County.
Rochester SMSA	Livingston, Monroe, Ontario, Orleans, and Wayne Counties.
Speculator	Hamilton County.
Ticonderoga	Essex County.
Utica-Rome SMSA	Herkimer and Oneida Counties.
Watertown	Jefferson County.
Watkins Glen	Schuyler County.
Wellsville	Allegany County.
North Carolina:	
Bryson City	Swain County.
Burgaw	Pender County.
Columbia	Tyrrell County.
Dunn	Harnett County.
Elizabethtown	Bladen County.
Lumberton	Robeson County.
Murphy	Cherokee County.
Raeford	Hoke County.
Roanoke Rapids	Halifax and Northampton Counties.
Robbinsville	Graham County.
Rocky Mount	Edgecombe and Nash Counties.
Snow Hill	Greene County.
Swan Quarter	Hyde County.
Warrenton	Warren County.
Wilmington SMSA	Brunswick and New Hanover Counties.
Windsor	Bertie County.
North Dakota:	
Kidder County	Kidder County.
McHenry County	McHenry County.
Rolla	Rolette County.
Ohio:	
Caldwell	Noble County.
Cambridge	Guernsey County.
Jackson	Jackson County.
Lima SMSA	Allen, Auglaize, Putnam, and Van Wert Counties.
Logan	Hocking County.
Manchester	Adams County.
Mansfield SMSA	Richland County.
McArthur	Vinton County.
Portsmouth	Scioto County.
Waverly	Pike County.
Youngstown-Warren SMSA.	Mahoning and Trumbull Counties.
Oklahoma:	
Antlers	Pushmataha County.
Coalgate	Coal County.
Holdenville	Hughes County.
Hugo	Choctaw County.
McAlester	Pittsburg County.
McIntosh County	McIntosh County.
Okmulgee-Henryetta	Okmulgee County.
Stigler	Haskell County.
Wilburton	Latimer County.
Oregon:	
Enterpise	Wallowa County.
Fossil	Wheeler County.
Grants Pass	Josephine County.
Hood River	Hood River County.
Prineville	Crook County.
Pennsylvania:	
Bedford	Bedford County.
Berwick-Bloomsburg	Columbia County.
Clearfield-Du Bois	Clearfield County; Rush Township, and Philipsburg and South Philipsburg Boroughs in Centre County.
Emporium	Cameron County.
Honesdale	Pike and Wayne Counties.
Huntingdon	Huntingdon County.
Johnstown SMSA	Cambria and Somerset Counties.
Kittanning-Ford City	Armstrong County.
Lewistown	Juniata and Mifflin Counties.
Lock Haven-Renovo	Clinton County.
Northeast Pennsylvania SMSA.	Lackawanna, Luzerne and Monroe Counties.
Philadelphia SMSA	Bucks, Chester, Delaware, Montgomery, and Philadelphia Counties, Pa.; Burlington, Camden, and Gloucester Counties, N.J.
Pittsburgh SMSA	Allegheny, Beaver, Washington and Westmoreland Counties.
Pottsville	Schuylkill County.
Reading SMSA	Berks County.
St. Marys	Elk County.
Sunbury-Shamokin-Mt. Carmel.	Montour, Northumberland Snyder, and Union Counties.
Tunkhannock	Wyoming County.
Uniontown-Connellsville.	Fayette County.
Waynesburg	Greene County.
Wellsboro	Tioga County.
Williamsport SMSA	Lycoming County.
Puerto Rico:	
Caguas SMSA	Caguas, Gurabo, and San Lorenzo Municipios.
Mayaguez SMSA	Anasco, Homigueros, and Mayaguez Municipios.
Ponce SMSA	Juana Diaz, Penuelas, Ponce, and Villalba Municipios.
San Juan SMSA	Bayamon, Canovanas, Carolina, Catano, Guaynabo, Loiza, San Juan, Toa Baja, and Trujillo Alto Municipios.
Remainder of Puerto Rico.	Puerto Rico less Caguas, Mayaguez, Ponce, and San Juan.[1]
Rhode Island:	
Providence-Warwick-Pawtucket SMSA.	Bristol, Kent, and Providence Counties, R.I.; towns of Exeter, Narragansett, New Shoreham, North Kingstown, Richmond, and South Kingstown, Washington County, R.I.; town of Jamestown, Newport County, R.I.; Attleboro City and towns of North Attleboro, Norton, Rehoboth, and Seekonk, Briston County, Mass.; Plainville Town in Norfolk County, Mass.; and towns of Blackstone and Millville in Worchester County, Mass.
Westerly	Towns of Charlestown, Hopkinton, and Westerly in Washington County.
South Carolina:	
Allendale	Allendale County.
Barnwell	Barnwell County.
Bennettsville	Marlboro County.
Bishopville	Lee County.
Charleston-North Charleston SMSA.	Berkeley, Charleston, and Dorchester Counties.
Chester	Chester County.
Dillon	Dillon County.
Georgetown	Georgetown County.
McCormick	McCormick County.
Ridgeland	Jasper County.
Sumter	Sumter County.
Union	Union County.
Walterboro	Colleton County.
South Dakota:	
Buffalo County	Buffalo County.
Corson County	Corson County.
Washabaugh County	Washabauga County.
Ziebach County	Ziebach County.
Tennessee:	
Athens	McMinn County.
Brownsville	Haywood County.
Crossville	Cumberland County.
Decatur	Meigs County.
Decaturville	Decatur County.
Dover	Stewart County.
Erin	Houston County.
Fayetteville	Lincoln County.
Gainesboro	Jackson County.
Greenville	Greene County.
Harriman-Rockwood	Roane County.
Humboldt	Gibson County.
Jamestown	Fentress County.
Lafollette-Jellico	Campbell County.
Lenoir	Loudon County.
Lexington	Henderson County.
Livingston	Overton County.
Newport	Cocke County.
Oneida	Scott County.
Savannah	Hardin County.
Selmer	McNairy County.
Sevierville	Sevier County.
Sneedville	Hancock County.
Somerville	Fayette County.
Sweetwater	Monroe County.
Tiptonville	Lake County.
Tracy City	Grundy County.
Waynesboro	Wayne County.
Texas:	
Brownsville-Harlingen San Benito SMSA.	Cameron County.
Carrizo Springs	Dimmit County.
Cotulla	La Salle County.
Crystal City	Zavala County.
Del Rio	Val Verde County.
Eagle Pass	Maverick County.
El Paso SMSA	El Paso County.
Galveston-Texas City SMSA.	Galveston County.
Laredo SMSA	Webb County.
Loving County	Loving County.
McAllen-Pharr-Edinburgh SMSA.	Hidalgo County.
Pearsall	Frio County.
Raymondsville	Willacy County.
Rio Grande City	Starr County.
Sabine County	Sabine County.
Texarkana SMSA	Bowie County, Tex., and Little River and Miller Counties, Ark.
Zapata	Zapata County.
Utah:	
Heber City	Wasatch County.
Manti	Sanpete County.
Panguitch	Garfield County.
Vermont:	
Newport	Orleans County; towns of Averill, Averys Gore, Bloomfield, Brighton, Brunswick, Canaan, Ferdinand, Lemington, Lewis, Norton, Warners Grant, and Warrens Gore in Essex County.
St. Johnsbury	Calendonia County except town of Groton and Ryegate; towns of Concord, East Haven, Granby, Guildhall, Lunenburg, Maidstone, and Victory in Essex County.
Virginia:	
Chincoteague	Accomack and Northampton Counties.

Quarterly List of Labor Surplus Areas for Eligibility Quarter Beginning October 1, 1978—Continued

Labor surplus area	Geographic description
Colonial Beach	Lancaster, Northumberland, Richmond, and Westmoreland Counties.
King and Queen County.	King and Queen County.
Lebanon	Dickenson and Russell Counties..
Lunenburg County	Lunenburg County.
Marion	Smyth County.
Norton-Big Stone Gap	Norton City and Wise County.
Surry County	Surry County.
Sussex County	Sussex County.
Washington:	
Aberdeen	Grays Harbor County.
Anacortes	Skagit County.
Bellingham	Whatcom County.
Centralia	Lewis County.
Colville	Stevens County.
Dayton	Columbia County.
Ellensburg	Kittitas County.
Goldendale	Klickitat County.
Longview	Cowlitz County.
Moses Lake	Grant County.
Newport	Pend Oreille County.
Oak Harbor	Island County.
Okanogan	Okanogan County.
Port Angeles	Clallam County.
Raymond	Pacific County.
Republic	Ferry County.
Stevenson	Skamania County.
Tacoma SMSA	Pierce County.
Wenatchee	Chelan and Douglas Counties.
Yakima SMSA	Yakima County.
West Virginia:	
Clay	Clay County.
Elkins	Randolph County.
Gassaway	Braxton County.
Grafton	Taylor County.
Grantsville	Calhoun County.
Hamlin	Lincoln County.
Hinton	Summers County.
Huntington-Ashland SMSA.	Cabell and Wayne Counties, W. Va.; Boyd and Greenup Counties, Ky; and Lawrence County, Ohio.
Kingwood	Preston County.
Logan-Madison	Boone and Logan Counties.
Oak Hill-Montgomery	Fayette County.
Parsons	Tucker County.
Pennsboro	Ritchie County.
Petersburg	Grant County.
Richwood	Nicholas County.
Ronceverte-White Sulphur Springs.	Greenbrier and Monroe Counties.
Webster Springs	Webster County.
Welch	McDowell County.
Weston	Lewis County.
Williamson	Mingo County.
Wisconsin:	
Ashland	Ashland County.
Bayfield	Bayfield County.
Crandon	Forest County.
Florence	Florence County.
Hayward	Sawyer County.
Hurley	Iron County.
Kenosha SMSA	Kenosha County.
Ladysmith	Rusk County.
Neopit	Menominee County.
Spooner	Washburn County.

[1]NOTE.—Deemed eligible based on the derived rate. No data are regularly estimated for small areas.

Signed at Washington, D.C., this 26th day of September 1978.

WILLIAM B. HEWITT,
Administrator, Office of Policy, Evaluation, and Research.

[FR Doc. 78-27516 Filed 9-28-78; 8:45 am]

[4510-26]

Occupational Safety and Health Administration

STANDARDS ADVISORY COMMITTEE ON CUTANEOUS HAZARDS

Meetings

Notice is hereby given that the Standards Advisory Committee on Cutaneous Hazards will meet on October 24 and 25, and November 20 and 21, 1978, in room N-5437 of the New Department of Labor Building, Third Street and Constitution Avenue NW., Washington, D.C.

The Standards Advisory Committee on Cutaneous Hazards was established under section 7(b) of the Occupational Safety and Health Act of 1970 (Pub. L. 91-596) to assist the Secretary of Labor in his standards-setting function.

Drafts of the Committee's report to OSHA will be discussed at the meetings. The meetings will begin at 9 a.m. The public is invited to attend.

For additional information contact: Mr. John M. Couric, Division of Consumer Affairs, U.S. Department of Labor, OSHA—Room N-3635, Third Street and Constitution Avenue NW., Washington, D.C. 20210, telephone 202-523-8024.

Written data or views concerning the Committee's assigned subjects may be submitted to the Division of Consumer Affairs. Such documents which are received before the scheduled meeting dates, preferably with 20 copies, will be presented to the committee and included in the official record of the proceedings.

Anyone who wishes to make an oral presentation should notify the Division of Consumer Affairs before the meeting date. The request should include the amount of time desired, the capacity in which the person will appear, and a brief outline of the content of the presentation. Oral presentations will be scheduled at the discretion of the chairman of the committee, to the extent which time permits.

Official records of the meetings will be available for public inspection at the Division of Consumer Affairs.

Signed at Washington, D.C. the 22d day of September 1978.

EULA BINGHAM,
Assistant Secretary.

[FR Doc. 78-27518 Filed 9-28-78; 8:45 am]

[4510-28]

Office of the Secretary

[TA-W-3548]

AIRCO WELDING PRODUCTS DIVISION OF AIRCO, INC., UNION, N.J.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3548: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 27, 1978 in response to a worker petition received on April 17, 1978 which was filed by the International Association of Machinists and Aerospace Workers on behalf of workers and former workers producing cutting and welding torches, regulators and valves, and electrical welding equipment at Airco Welding Products Division of Airco, Inc., Union, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on May 16, 1978 (43 FR 21069). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Airco, Inc., Airco Welding Products Division of Airco, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. With respect to workers employed in the Electrical Welding Equipment Department and workers employed in the Regulator Department of Airco Welding Products Division of Airco, Inc., Union, N.J., without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that customers of Airco Welding Products Division of Airco, Inc., Union, N.J. purchased neither imported regulators or valves nor electrical welding equipment during the period under investigation.

With respect to workers in the Torch Department and workers in the Primary Machining Department at Airco Welding Products Division of Airco, Inc., Union, N.J., all of the

group eligibility requirements of section 222 of the act have been met.

U.S. imports of gas welding and cutting equipment increased absolutely in 1977 from 1976 and increased absolutely and relative to domestic production in the first half of 1978 compared to the first half of 1977.

Airco Welding Products began importing torches in early 1978.

CONCLUSIONS

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with cutting and welding torches produced by Airco Welding Products Division of Airco, Inc., Union, N.J. contributed importantly to the decline in production of cutting and welding torches and to the separation of workers in the Torch Department and workers in the Primary Machining Department of Airco Welding Products Division. In accordance with the provisions of the act, I make the following certification:

All workers employed in the Torch Department and all workers employed in the Primary Machining Department at Airco Welding Products Division of Airco, Inc., Union, N.J., who became totally or partially separated after August 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further determine that all workers in the Electrical Welding Equipment Department and in the Regulator Department of Airco Welding Products Division of Airco, Inc., Union, N.J. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974. Signed at Washington, D.C. this 20th day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27519 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3724]

ANGIE CLOTHING CO., INC., NEWBURGH, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3724: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 18, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing ladies' winter and spring coats at Angie Clothing Co., Inc., Newburgh, N.Y. The investigation revealed that Angie Clothing Co., produces ladies' wool coats and raincoats.

The Notice of Investigation was published in the FEDERAL REGISTER on June 13, 1978 (43 FR 25498-99). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Angie Clothing Co., its customers, the U.S. International Trade Commission, the U.S. Department of Commerce, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

Sales and production of women's raincoats and wool coats by Angie increased from 1976 to 1977 and increased during the first 5 months of 1978 compared to the first 5 months of 1977.

CONCLUSION

After careful review I determine that workers of Angie Clothing Co., Inc., Newburgh, N.Y., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27520 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2811]

ARMCO STEEL CORP., KANSAS CITY WORKS, KANSAS CITY, MO.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2811: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on December 27, 1977, in response to a worker petition received on December 9, 1977, which was filed by the United Steelworkers of America on behalf of workers and former workers producing wire rope, cables, and bead wire at the Kansas City Works, Kansas City, Mo., of Armco Steel Corp. During the course of the investigation, it was determined that wire rod and products, hot rolled products, reinforcing bars, fasteners, and fence posts are produced at the Kansas City Works.

The Notice of Investigation was published in the FEDERAL REGISTER on January 1, 1978 (43 FR 1555). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from information and publications provided by officials of Armco Steel Corp., its customers, the American Iron and Steel Institute, the U.S. Department of Commerce, the United States International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. The investigation revealed that, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That a significant number or proportion of the workers in the worker's firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

Evidence developed during the Department's investigation revealed that the average number of production workers at the Kansas City Works increased in 1977 compared to 1976 and in the first 6 months of 1978 compared to the same period of 1977. There were no significant partial separations during this period.

There is no immediate threat of separations to workers at the Kansas City Works.

CONCLUSION

After careful review, I determine that workers of the Kansas City Works, Kansas City, Mo., of Armco Steel Corp. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27521 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2871]

ARMCO STEEL CORP., METAL PRODUCTS DIVISION, FAIRBANKS, TEX.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-2871: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 9, 1978, in response to a worker petition received on December 19, 1977, which was filed by the United Steelworkers of America on behalf of workers and former workers producing drainage products and highway guardrails at the Fairbanks, Tex., plant of Armco Steel Corp., Metal Products Division. The investigation revealed that steel tanks and pressure vessels are produced at the Fairbanks plant.

The Notice of Investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3778). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Armco Steel Corp., its customers, the Steel Plate Fabricators Association, the U.S. Department of Commerce, the United States International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced at the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The investigation revealed that U.S. imports of metal tanks and vessels have always been small relative to domestic production. The imports to domestic production ratio reached its highest level in the last 5 years at only 0.67 percent in 1976 as the value of imports increased to $14.5 million compared to $6.1 million in 1975. In 1977, the value of imports declined to $8.6 million and the imports to domestic production ratio decreased to 0.29 percent.

Customers surveyed by the Department had not purchased imported steel tanks and vessels in 1975, 1976, or 1977.

CONCLUSION

After careful review I determine that all workers of the Fairbanks, Tex., plant of Armco Steel Corp., Metal Products Division, are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-27522 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2870]

ARMCO STEEL CORP. METAL PRODUCTS DIVISION MEMPHIS, TENN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2870: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 9, 1978 in response to a worker petition received on December 19, 1977, which was filed by the United Steelworkers of America on behalf of workers and former workers producig drainage products and highway guard rails at the Memphis, Tenn. plant of Armco Steel Corp., Metal Products Division. The investigation revealed that corrugated steel pipe is produced at the Memphis plant.

The Notice of Investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3778). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Armco Steel Corp., its customers, the National Corrugated Steel Pipe Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced at the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

United States imports of corrugated steel pipe are negligible according to both industry and United States Government sources. A survey of Armco Steel Corp. customers by the department revealed that none of these customers purchased any imported corrugated steel pipe in 1975, 1976, or 1977.

CONCLUSION

After careful review, I determine that all workers of the Memphis, Tenn., plant of Armco Steel Corp., Metal Products Division are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 70-27523 Filed 9-28-78; 8:45am]

[4510-28]

[TA-W-2869]

ARMCO STEEL CORP. METAL PRODUCTS DIVISION, SOUTH BEND, IND.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2869: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 9, 1978 in response to a worker petition received on December 19, 1977, which was filed by the United Steelworkers of America on behalf of workers and former workers producing drainage products and highway guard rails at the south Bend, Ind. plant of armco steel Corp., Metal Products Division. the investigation revealed that corrugated steel pipe is produced at the South Bend plant.

The Notice of Investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3778). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Armco Steel Corp., its customers, the National Corrugated Steel Pipe Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment as-

sistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of corrugated steel pipe are negligible according to both industry and U.S. Government sources. A Departmental survey of the subject firm's customers representing a substantial proportion of sales revealed that none of these customers purchased any imported corrugated steel pipe in 1975, 1976 or 1977.

CONCLUSION

After careful review I determine that all workers of the South Bend, Ind. plant of Armco Steel corp., Metal Products Division are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 21st day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27524 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3408]

ARTEX INDUSTRIES, INC., JERSEY CITY, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3408: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 27, 1978 in response to a worker petition received on March 7, 1978 which was filed on behalf of workers and former workers producing fabricated marble and granite at the marble shop of Artex Industries, Inc., Jersey City, N. J.

The Notice of Investigation was published in the FEDERAL REGISTER on April 11, 1978 (43 FR 15205). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Artex Industries, Inc., its major competitors, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of finished and unfinished dimension marble increased from $12,218 thousand in 1976 to $13,568 thousand in 1977 and rose from $2,910 thousand in the first quarter of 1977 to $3,964 thousand in the first quarter of 1978. The ratio of imports to domestic marble shipments was 118.4 percent in 1976 and 116.9 percent in 1977.

U.S. imports of finished and unfinished dimension granite decreased from $6,903 thousand in 1976 to $6,729 thousand in 1977 and declined from $1,819 thousand in the first quarter of 1977 to $1,775 thousand in the first quarter of 1978. The ratio of imports to domestic granite shipments was 12.3 percent in 1976 and 1977.

In late 1977 Artex Industries lost bids on major marble contracts. The 1977 Artex Industries lost bids on major marble contracts. The contracts were awarded to companies which relied primarily upon prefabricated imported marble to complete the work specified in the contracts. As a result of this loss of business, Artex closed its marble shop in February 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with fabricated marble and granite produced at the marble shop of Artex Industries, Inc., Jersey City, N. J. contributed importantly to the decline in sales or production and to the total or partial separations of workers at the company. In accordance with the provisions of the Act, I make the following certification:

All workers of the marble shop of Artex Industries, Incorporated, Jersey City, N.J. who became totally or partially separated from employment on or after November 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27525 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3815]

ATLANTIC HIGHLANDS MANUFACTURING CO., HIGHLANDS, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3815: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 7, 1978 in response to a worker petition received on June 2, 1978 which was filed on behalf of all workers producing children's coats at the Highlands, N.J. plant of the Atlantic Highlands Manufacturing Co.

The Notice of Investigation was published in the FEDERAL REGISTER on June 20, 1978 (43 FR 26499). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Atlantic Highlands Manufacturing Co., its customer, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the group eligibility requirements have been met.

Imports of women's, misses', and children's coats and jackets increased 20.9 percent from 1976 to 1977 from 2,252 thousand dozen in 1976 to 2,723 dozen in 1977. The ratio of imports to U.S. production of women's, misses', and children's coats and jackets increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department of Labor surveyed the main customer buying children's coats from Atlantic Highlands Manufacturing Co. This customer indicated that he reduced purchases of children's coats from Atlantic Highlands Manufacturing Co. and increased purchases of imports in fiscal year 1978 compared to fiscal year 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with children's coats produced at the Atlantic Highlands Manufacturing Co., Highlands, N.J. contributed importantly to the decline in sales or production and to the total or partial separation of the workers at this plant. In accord-

ance with the provisions of the Act, I make the following certification:

All workers of the Atlantic Highlands Manufacturing Co., Highlands, N.J. who became totally or partially separated from employment on or after May 31, 1977 and before April 1, 1978 are eligible to apply for adjustment assistance under title II, Chapter 2 of the Trade Act of 1974. All workers separated on or after April 1, 1978 are denied eligibility to apply for adjustment assistance benefits.

Signed at Washington, D.C. this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27526 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3270]

BARO CORP., HAVERHILL, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3270: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 1, 1978 in response to a worker petition received on February 21, 1978 which was filed on behalf of workers and former workers producing shoe uppers at Baro Corp., Haverhill, Mass.

The Notice of Investigation was published in the FEDERAL REGISTER on March 14, 1978 (43 FR 10649). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Baro Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with the articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that U.S. imports of shoe uppers are negligible. The ratio of imports to domestic production of shoe uppers was 2.1 percent or less from 1973 through the first quarter of 1978.

Shoes are not like or directly competitive with shoe uppers.

A survey by the Department indicated that Baro Corp. performs the major proportion of its contract work for a single shoe manufacturer. This manufacturer did not import shoe uppers during the period from January 1975 to March 1978. Sales of finished shoes by the manufacturer increased in 1977 compared to 1976 and in the first quarter of 1978 compared to the same period of 1977.

CONCLUSION

After careful review, I determine that all workers of Baro Corp., Haverhill, Mass. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27527 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3462]

BLAIR FOOTWEAR, INC., ALTOONA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3462: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 4, 1978, in response to a worker petition received on March 24, 1978, which was filed on behalf of workers and former workers producing women's dress and casual shoes at Blair Footwear, Inc., Altoona, Pa. During the course of the investigation, it was established that the firm produces both rubber and nonrubber women's footwear.

The notice of investigation was published in the FEDERAL REGISTER on April 28, 1978 (43 FR 18360-61). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Blair Footwear, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

United States imports of women's nonrubber, nonathletic footwear increased from 183.5 million pairs in 1975 to 183.8 million pairs in 1976 and then decreased to 171.9 million pairs in 1977. Imports increased to 53.3 million pairs during the first quarter of 1978 compared to 45.5 million pairs for the same period in 1977.

The ratio of imports to domestic production for women's nonrubber, nonathletic footwear increased from 117.9 percent in 1976 to 122.8 percent in 1977. The ratio of imports to domestic production increased to 138.4 percent in the first quarter of 1978 compared to 127.8 percent for the same period in 1977.

United States imports of rubber/canvas footwear increased from 23.6 million pairs in 1975 to 31.9 million pairs in 1976, and then decreased to 24.2 million pairs in 1977.

The ratio of imports to domestic production for rubber/canvas footwear increased from 17.6 percent in 1975 to 26.6 percent in 1976, and increased again to 27.9 percent in 1977.

A survey of the customers of Blair Footwear, Incorporated revealed that customers have increased purchases of imported women's footwear in each year from 1975 to 1977, and increased purchases of imported women's footwear in the first quarter of 1978 compared to the first quarter of 1977. A number of customers reduced purchases from Blair Footwear, Inc. in the first quarter of 1978 compared to the first quarter of 1977, and had increased purchases of imported women's footwear over the same period.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with women's rubber and nonrubber footwear produced by Blair Footwear, Inc., Altoona, Pa. contributed importantly to the decline in sales and production and to the total or partial separation of workers at the plant. In accordance with the provisions of the Act, I make the following certification:

All workers at Blair Footwear, Inc., Altoona, Pa. who became totally or partially separated from employment on or after December 3, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 21st day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research

[FR Doc. 78-27528 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3519]

BOEING VERTOL CO., EDDYSTONE, PA.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3519: Investigation regarding certification of eligibility to apply for adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on April 18, 1978 in response to a worker petition received on April 4, 1978 which was filed on behalf of workers and former workers producing standard light rail trolleys at the Boeing Vertol Co., Eddystone, Pa.

The Department's investigation revealed that workers at the Boeing Vertol Co. also fabricate helicopters. This petition is expanded to cover workers engaged in employment related to the production of helicopters at the Boeing Vertol Co., Eddystone, Pa., at Boeing Vertol's warehouses in Morton, Pa. and Chester, Pa. and at Boeing Vertol's test facilities in Philadelphia, Pa. and Wilmington, Del.

The Notice of Investigation was published in the FEDERAL REGISTER on May 2, 1978 (43 FR 18789). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Boeing Vertol Co., the United States International Trade Commission, U.S. Department of Commerce, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. With respect to workers producing helicopters, without regard to whether any of the other criteria have been met the following criterion has not been met:

> That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separation, or threat thereof, and to the absolute decline in sales or production."

Boeing Vertol produces CH47 Chinook helicopters for the U.S. Army and for sale to foreign governments. Conforming to provisions in the Defense Appropriations Act of the 92d Congress restricting the importation of defense related articles, there are no imports of military helicopters into the United States.

With respect to workers producing surface transport vehicles all of the group eligibility requirements of section 222 of the act have been met.

Imports of surface transport vehicles fabricated in 1977 and 1978 with expected shipment into the United States in 1979 are expected to increase substantially based on available data on contracts let to foreign suppliers of surface transport vehicles.

Boeing Vertol recently lost a major contract to fabricate surface transport vehicles to foreign competition. The company was the low domestic bidder to fabricate "arcticulated" vehicles for the Cleveland Transit Authority. Another domestic firm submitted a lower bid, but for a "non-articulated" car. The competition was won by an Italian firm which will supply the Cleveland Transit Authority with "articulated" vehicles.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases in imports of articles like or directly competitive with surface transport vehicles produced at the Boeing Vertol Co., Eddystone, Pa. contributed importantly to the decrease in sales and production and to the total or partial separations of workers at that firm. In accordance with the provisions of the act, I make the following certification:

> All workers of the Boeing Vertol Co., Eddystone, Pa, engaged in employment related to the production of surface transport vehicles who became totally or partially separated from employment on or after March 31, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

I further conclude that workers engaged in employment related to the production of helicopters at the Boeing Vertol Co., Eddystone, Pa., at Boeing Vertol's warehouses in Morton, Pa. and Chester, Pa. and at Boeing Vertol's test facilities in Philadelphia, Pa. and Wilmington, Del. be denied eligibility to apply for adjustment assistance.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27543 Filed 9-28-78; 8:45 am]

[TA-W-3254]

BOGART INDUSTRIES, INC., FORT WORTH; JACKSBORO; CLEBURN: AND DUBLIN, TEX.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance; Correction

In FEDERAL REGISTER Doc. 78-24319 appearing on pages 38636-38637 in the FEDERAL REGISTER of August 29, 1978, one of the subject units covered in that certification is identified as the Dublin, Tex., plant of Bogart Industries, Inc. It should be corrected to read "Dublin Industries, Dublin, Tex."

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 70-27529 Filed 9-28-78; 8:45am]

[4510-28]

[TA-W-3859]

BRIDON AMERICAN CORP., LINDEN, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3859: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Linden, N.J. service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Linden facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers

where the wire rope is cut to the individual customer's requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope, who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp., have contributed importantly to the total or partial separation of workers at the Linden, N.J. service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Linden, N.J. service center of the Bridon, American Corp., who became totally or partially separated from employment on or after June 8, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27530 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3863]

BRIDON AMERICAN CORP., MEMPHIS, TENN.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3863: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978 in response to a worker petition received on June 12, 1978 which was filed on behalf of workers and former workers distributing wire products at the Memphis, Tenn. service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Memphis facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of ge b29se3.163the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976 were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980 unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Memphis, Tenn. service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Memphis, Tenn. service center of the Bridon American Corp. who became totally or partially separated from employment on or after November 1, 1977 are eligible to apply for adjustment assistance benefits under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27531 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3862]

BRIDON AMERICAN CORP., MELVINDALE, MICH.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3862: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Melvindale, Mich., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Melvindale facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Melvindale, Mich. service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Melvindale, Mich. service center of the Bridon American Corp. who became totally or partially separated from employment on or after January 1, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27532 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3861]

BRIDON AMERICAN CORP., LOMBARD, ILL.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3861: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products to customers at the Lombard, Ill., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Lombard facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSIONS

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp., have contributed importantly to the total of partial separation of workers at the Lombard, Ill., service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Lombard, Ill., service center of the Bridon American Corp., who become totally or partially separated from employment on or after June 8, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27533 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3860]

BRIDON AMERICAN CORP., SYRACUSE, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3860: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Syracuse, N.Y., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Syracuse facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the fact obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp., have contributed importantly to the total or partial separation of workers at the Syracuse, N.Y., service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Syracuse, N.Y., service center of the Bridon American Corp. who became totally or partially separated from employment on or after November 1, 1977, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27534 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3858]

BRIDON AMERICAN CORP., JEFFERSON, LA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3858: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Jefferson, La., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the United States Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Jefferson facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Jefferson, La., service center of that firm. In accordance with the provisions of the Act, I make the following certification:

All employees of the Jefferson, La., service center of the Bridon American Corp. who because totally or partially separated from employment on or after June 8, 1977, are eligible to apply for adjustment assistance under title III, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27535 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3857]

BRIDON AMERICAN CORP., ATLANTA, GA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3857: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978, in response to a worker petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Atlanta, Ga., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Atlanta facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp., have contributed importantly to the total or partial separation of workers at the Atlanta, Ga., service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Atlanta, Ga., service center of the Bridon American Corp., who became totally or partially separated from employment on or after November 1, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27536 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3856]

BRIDON AMERICAN CORP., DENVER, COLO.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3856: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 9, 1978, in response to a worker

petition received on June 12, 1978, which was filed on behalf of workers and former workers distributing wire products at the Denver, Colo., service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Denver facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976, were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980, unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the fact obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp., have contributed importantly to the total or partial separation of workers at the Denver, Colo., service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Denver, Colo., service center of the Bridon, American Corp., who became totally or partially separated from employment on or after January 1, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27537 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3854]

BRIDON AMERICAN CORP., HOUSTON, TEX.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3854: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978 in response to a worker petition received on June 12, 1978 which was filed on behalf of workers and former workers distributing wire products at the Houston, Tex. service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The Houston facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976 were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980 unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Houston, Tex. service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Houston, Texas service center of the Bridon American Corp. who became totally or partially separated from employment on or after November 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27538 File 9-28-78; 8:45 am]

[4510-28]

[TA-W-3864]

BRIDON AMERICAN CORP., PITTSBURGH, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3864: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978 in response to a worker petition received on June 12, 1978 which was filed on behalf of workers and former workers distributing wire products at the Pittsburgh, Pa. service center of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp. its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met. It is

concluded that all of the requirements have been met.

The Pittsburgh facility is a service and distribution center for wire rope which is produced at the company's manufacturing facilities. All of the wire rope produced by the company is shipped to the distribution centers where the wire rope is cut to the individual customers' requirements. The wire rope is then shipped from the center to the customers. The functions performed at the centers are integral to the company's production of wire rope. Workers engaged in employment related to the production of a significant percentage of the company's total 1977 production of wire rope who became totally or partially separated from employment on or after October 31, 1976 were certified eligible to apply for adjustment assistance benefits on April 14, 1978. This determination will expire April 14, 1980 unless terminated earlier by the Secretary of Labor. See Department determination TA-W-2609.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Pittsburgh, Pa. service center of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Pittsburgh, Pennsylvania service center of the Bridon American Corp. who became totally or partially separated from employment on or after January 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27539 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3865]

BRIDON AMERICAN CORP., WILKES-BARRE, PA.

Certification Regarding Eligibility To Apply for Workers Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3865: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 19, 1978 in response to a worker petition received on June 12, 1978 which was filed on behalf of workers and former workers of the Wilkes-Barre, Pa. Corporate Headquarters of the Bridon American Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28581). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Bridon American Corp., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Trade Act of 1974 must be met. It is concluded that all of the requirements have been met.

The administrative offices of the Bridon American Corp. in Wilkes-Barre, Pa. perform activities necessary to the support of the company's production operations. Workers engaged in employment related to the production of a significiant percentage of the company's total 1977 production who became totally or partially separated from employment on or after October 31, 1976 have previously been certified eligible to apply for adjustment assistance benefits in the Department's determination on TA-W-2609 which is dated April 14, 1978. The certification will remain in effect until April 14, 1980 unless terminated earlier by the Secreatry of Labor.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competative with the wire rope produced by the Bridon American Corp. have contributed importantly to the total or partial separation of workers at the Wilkes-Barre, Pa. Corporate Headquarters of that firm. In accordance with the provisions of the act, I make the following certification:

All employees of the Wilkes-Barre, Pa. Corporate Headquarters of the Bridon American Corp. who became totally or partically separated from employment on or after December 1, 1977 are eligible to apply for adjustment assistance benefits under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27540 Filed 9-28-78 8:45 am]

[4510-28]

[TA-W-3566]

BRUNSWICK PULP AND PAPER CO., BRUNSWICK, GA.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on May 3, 1978 in response to a worker petition received on April 19, 1978 which was filed by the United Paper Workers International Union on behalf of workers and former workers producing bleached pulp and paper board at the Brunswick, Ga. plant of Brunswick Pulp and Paper Co.

The Notice of Investigation was published in the FEDERAL REGISTER on May 16, 1978 (43 FR 21068-69). No public hearing was requested and none was held.

The petitioner, the United Paper Workers International Union, requested withdrawal of the petition. On the basis of the withdrawal, continuing the investigation would serve no purpose. Consequently, the investigation has been terminated. Signed at Washington, D.C. this 15th day of September, 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27544 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3585]

BRUTIN & CO., INC., PATERSON, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3585: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats and suits at Brutin & Co., Inc., Paterson, N.J. The investigation revealed that Brutin & Co., Inc., no longer make suits.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Brutin & Co., Inc., its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade

Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252,000 dozen in 1976 to 2,723,000 dozen in 1977. Imports declined from 590,000 dozen in the first quarter of 1977 to 572,000 dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturers for which Brutin & Co., Inc., worked in 1976 and 1977. Manufacturers that accounted for a majority of sales in 1976 maintained constant purchases from Brutin & Co., Inc., and increased purchases of imported ladies' coats in 1977 compared to 1976. Manufacturers that accounted for a majority of sales in 1977 decreased purchases from Brutin & Co., Inc., and increased purchases of imported ladies' coats in the first quarter of 1978 compared to the first quarter of 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' coats produced at Brutin & Co., Inc., Paterson N.J. contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Brutin & Co., Inc., Paterson, N.J. who became totally or partially separated from employment on or after October 1, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27541 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3454]

BUCKHANNON, W. VA. PLANT REIDBORD BROTHERS CO., INC.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3454: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 30, 1978 in response to a worker petition received on March 21, 1978 which was filed on behalf of workers and former workers producing men's slacks at Reidbord Brothers Co., Buckhannon, W. Va.

The investigation revealed that the workers of the Buckhannon, W. Va. plant of Reidbord Brothers Co., Inc. produced men's slacks, walking shorts, and knit tennis shorts.

The Notice of Investigation was published in the FEDERAL REGISTER on April 25, 1978 (43 FR 17551). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Reidbord Brothers Co., Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The investigation has revealed that all of the requirements have been met.

U.S. imports of men's and boy's dress and sport trousers and shorts increased from 55,508,000 units in 1975 to 73,209,000 units in 1976 and increased to 76,419,000 units in 1977. Imports increased to 24,039,000 units during the first quarter of 1978 compared to 17,152,000 units during the same period in 1977. The ratio of imports to domestic production increased from 34.1 percent in 1975 to 40.9 percent in 1976, and then decreased to 38.0 percent in 1977.

Customers of Reidbord Brothers Co., Inc., who were surveyed indicated that they decreased purchases of slacks from the subject firm and increased purchases of slacks from foreign sources in 1977 compared to 1976.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases of imports of articles like or directly competitive with men's slacks, walking shorts, and knit tennis shorts produced at the Buckhannon, W. Va. plant of Reidbord Brothers Co., Inc. contributed importantly to the decline in sales or production and to the total or partial separations of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers of the Buckhannon, W. Va. plant of Reidbord Brothers Co., Inc., who became totally or partially separated from employment on or after March 16, 1977 and before October 21, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. All workers separated on or after October 21, 1977 are denied eligibility to apply for adjustment assistance benefits.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27545 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2898]

BURLINGTON DRESS CO., ATLANTIC CITY AND BURLINGTON, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2898: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 11, 1978 in response to a worker petition received on December 27, 1977, which was filed by the International Ladies Garment Workers Union on behalf of workers and former workers producing ladies' dresses and sportswear at the Burlington, N.J. plant of Burlington Dress Co. The investigation was expanded to include workers and former workers producing ladies' dresses and sportswear at the Atlantic City, N.J. plant of Burlington Dress Co.

The Notice of Investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3776). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Burlington Dress Co., its customers, the U.S. Department of Commerce, the United States International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the

separations, or threats thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that U.S. imports of women's and misses' dresses increased from 645 thousand dozen in 1975 to 659 thousand dozen in 1976. The ratio of imports to domestic production remained unchanged at 4.5 percent in 1975 and 1976. Imports decreased from 659 thousand dozen in 1976 to 587 thousand dozen in 1977, a decline of 10.9 percent.

A survey of clothing manufacturers who provided contract work to Burlington Dress Co. indicated that the manufacturers did not use foreign contract firms and did not purchase imports of finished ladies' dresses and sportswear. A secondary survey of retail stores who purchased ladies' dresses from the clothing manufacturers revealed that the retail stores either increased purchases from the clothing manufacturers or did not import any dresses in 1976 and 1977.

CONCLUSION

After careful review I determine that all workers of the Atlantic City and Burlington, N.J. plants of Burlington Dress Co. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMERS F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27542 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3613]

CERRO COAT, INC., HOBOKEN, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3613: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats at Cerro Coat, Inc., Hoboken, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Cerro Coat, its customers (manufacturers), the U.S. Department of Commerce, the United States International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports declined from 590 thousand dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturers for which Cerro Coat worked in 1977 and 1978. Manufacturers that accounted for a majority of sales in 1977 reduced purchases from Cerro Coat and increased purchases of imported ladies' coats in the first quarter of 1978 compared to the first quarter of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' coats produced at Cerro Coat, Inc., Hoboken, N.J., contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the Act, I make the following certification:

All workers of Cerro Coat, Inc., Hoboken, N.J., who became totally or partially separated from employment on or after October 7, 1977 and before May 1, 1978 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974. All workers who became totally or partially separated from employment on or after May 1, 1978 are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27546 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2759]

CHAIN BIKE CORP. ALLENTOWN, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2759: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on December 12, 1977, in response to a worker petition received on December 1, 1977 which was filed by the International Brotherhood of Teamsters on behalf of workers and former workers producing bicycles at Chain Bike Corp., Allentown, Pa.

The Notice of Investigation was published in the FEDERAL REGISTER on December 30, 1977 (42 FR 65306). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Chain Bike Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion as not been met.

That sales of production, or both, of such firm or subdivision have decreased absolutely.

The Department's investigation revealed that sales and production of bicycles at Chain Bike Corp. increased in 1977 compared to 1976, and increased in the first half of 1978 compared to the same period of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I determine that all workers of Chain Bike Corp., Allentown, Pa. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27547 Filed 9-28-78 8:45 am]

[4510-28]

[TA-W-3837]

CIBA-GEIGY CORP., DYESTUFFS AND CHEMICALS DIVISION, BAYONNE, N.J.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on June 14, 1978 in response to a worker petition received on June 5, 1978 which was filed by the International Chemical Workers producing dyes for the textile industry.

Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27924). No public hearing was requested and none was held.

During the course of the investigation, it was established that all workers were separated from the employment of the Dyestuffs and Chemicals Division of Ciba-Geigy Corp. in January 1977. Section 223(b)(1) of the Trade Act of 1974 states that certification under this section shall not apply to any worker whose last total or partial separation from the firm or appropriate subdivision of the firm occurred more than 12 months before the date of filing under Title II, Chapter 2 of the Trade Act of 1974.

The filing date of the petition in this case is June 5, 1978. Since workers separated from the employment of the Dyestuffs and Chemical Division prior to June 5, 1977 are not eligible for program benefits under Title II, Chapter 2, Subchapter B of the Trade Act of 1974, continuation of this investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 20th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27548 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3168]

CLIFTON CLOTHING CO., WALLINGTON, N.J.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3168: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 21, 1978 in response to a worker petition received on February 6, 1978 which was filed on behalf of workers and former workers producing men's and ladies' tailored jackets at Clifton Clothing Co., Wallington, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8864). No public hearing was requested and none was held.

On February 17, 1976, the Department issued a certification of eligibility to apply for adjustment assistance for all workers of Clifton Clothing Co. That certification remained in effect until February 17, 1978—2 years from the date of issuance.

The information upon which the determination was made was obtained principally from officials of Clifton Clothing Co., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That a significant number or proportion of workers in the workers' firm, or an appropriate subdivision thereof, have become totally or partially separated or are threatened to become totally or partially separated.

Average annual employment of production workers of Clifton Clothing Co., Wallington, N.J. increased by 2 percent during the first quarter of 1978 compared to the fourth quarter of 1977, increased 13 percent during the second quarter of 1978 compared to the first quarter of 1977, and increased 7 percent during the first half of 1978 compared to the same period in 1977. Average hours worked increased 36 percent during the second quarter of 1978 compared to the first quarter of 1978 and increased 24 percent during the first half of 1978 compared to the same period in 1977.

CONCLUSION

After careful review, I determine that all workers of Clifton Clothing Co., Wallington, N.J. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27549 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3410]

DAYTON MALLEABLE, INC. OHIO MALLEABLE DIVISION, COLUMBUS, OHIO

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3410: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 27, 1978, in response to a worker petition received on March 9, 1978, which was filed by the United Steelworkers of American on behalf of workers and former workers producing malleable castings at Dayton Malleable, Inc., Ohio Malleable Division, Columbus, Ohio.

The Notice of Investigation was published in the FEDERAL REGISTER on April 11, 1978 (43 FR 15205). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Dayton Malleable, Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met.

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absoluted decline in sales or production.

Evidence developed during the Department's investigation revealed that production workers at the Ohio Malleable Division were on strike from November 1, 1977, to February 4, 1978. From March 7, 1977, the earliest possible impact date, until the strike, total separations were not significant.

As a consequence of the strike, customers recalled patterns from the firm and shifted production to other domestic firms. The failure to recall workers following settlement of the strike is attributable to the shift of business rather than to import competition.

CONCLUSION

After careful review, I determine that all workers at the Ohio Malleable

Division, Columbus, Ohio of Dayton Malleable, Inc. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27550 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3434]

DAYTON MALLEABLE INC., IRONTON DIVISION, IRONTON, OHIO

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3434: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 28, 1978, in response to a worker petition received on March 10, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing malleable castings at Dayton Malleable Incorporated, Ironton Division, Ironton, Ohio.

The Notice of Investigation was published in the FEDERAL REGISTER on April 11, 1978 (43 FR 15205). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Dayton Malleable Incorporated, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met, without regard to whether any of the other criteria have been met, the following criterion has not been met.

That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed during the Department's investigation revealed that production workers at the Ironton Division were on strike from November 1, 1977 to February 4, 1978. From March 7, 1977, the earliest possible impact date, until the strike, employment increased.

As a consequence of the strike, customers recalled patterns from the firm and shifted production to other domestic firms. The failure to recall workers following settlement of the strike is attributable to this shift of business rather than to import competition.

CONCLUSION

After careful review, I determine that all workers at the Ironton Division of Dayton Malleable, Inc., are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27551 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-2-3718]

DEE-MURE BRASSIERE CO., INC., HAMLIN, W. VA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3718: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 16, 1978, in response to a worker petition received on May 15, 1978, which was filed by the International Ladies Garment Workers Union on behalf of workers and former workers producing brassieres and body suits at Dee-Mure Brassiere Co., Inc., Hamlin, W. Va. The investigation revealed that the workers produced brassieres.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27923-24). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Dee-Mure Brassiere Co., Inc., its customers, the U.S. Department of Commerce, the American Textile Manufacturers' Institute, the National Cotton Council of America, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met. It is concluded that all the requirements have been met.

U.S. imports of brassieres, bra-lettes, and bandeaux increased absolutely and relative to domestic production and consumption in 1976 compared to 1975, and increased absolutely in 1977 compared to 1976 and increased in the first quarter of 1978 compared to the first quarter of 1977.

Dee-Mure was a contractor who produced for a single customer. The customer began importing brassieres in July 1976, increased imports in the period from July through December 1977 compared to the same period in 1976, and increased imports in the first half of 1978 compared to the first half of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases in imports of articles like or directly competitive with brassieres produced at Dee-Mure Brassiere Co., Inc., Hamlin, W. Va., contributed importantly to the decline in production and to the total or partial separations of workers at that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Dee-Mure Brassiere Co., Inc., Hamlin, W. VA., who became totally or partially separated from employment on or after May 11, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27552 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3826]

DIXIE SHOE CORP. EUFAULA, ALA.

Certification Regaridng Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3826: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 12, 1978, in response to a worker petition received on June 6, 1978, which was filed on behalf of workers and former workers producing ladies' footwear at Dixie Shoe Corp., Eufaula, Ala.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27925). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officals of Dixie Shoe Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. The investigation has revealed that all of the requirements have been met.

The Department's investigation revealed that imports of women's nonrubber footwear increased from 183.5 million pairs in 1975 to 183.8 million pairs in 1976. Imports declined in 171.9 million pairs in 1977; however the ratio of imports to domestic production increased from 117.9 percent to 122.8 percent from 1976 to 1977. Imports of women's nonrubber footwear increased both absolutely and relative to domestic production in the first quarter of 1978 compared to the like period of 1977.

In its report to the President of February 8, 1977, the U.S. Internationl Trade Commission found that certain footwear articles are being imported into the United States in such increased quantities as to be a substantial cause of serious injury to the domestic industry producing such articles. The Commission considered other factors that have been alleged as more important causes such as the recent re-cession, inability of manufactures to keep pace with technological and style changes, and decreased productivity. However, the Commission concluded that, although such a factors may have contributed in part, imports have been the most important cause of injury.

A survey of Dixie Shoe customers indicated that a major customer reduced purchases from Dixie while increasing import purchases during the first half of 1978 compared to the same period of 1977

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increase of imports like or directly competitive with ladies' footwear produced at Dixie Shoe Corp., Eufaula, Ala., contributed importantly to the decline in sales or production and to the total or partial separation of workers at such plant.

In accordance with the provisions of the act, I make the following certification:

All workers at Dixie Shoe Corp., Eufaula, Ala., who became totally or partially separated from employment on or after June 2, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Mangement, Administration and Planning

[FR Doc. 78-27553 Filed 9-28-78 8:45 am]

[4510-28]

[TA-W-3748]

E & W OF ILLMO, INC., ILLMO, MO.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3748: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 23, 1978, in response to a worker petition received on May 15, 1978, which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing boys' and men's jeans and overalls at E & W of Illmo, Inc., Illmo, Mo.

The Notice of Investigation was published in the FEDERAL REGISTER on June 6, 1978 (43 FR 24633). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Ely & Walker, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The investigation revealed that all of the criteria have been met.

United States imports of men's and boys' woven cotton and manmade fiber work trousers and one-piece suits increased from 9.2 million units in 1976 to 50.6 million units in 1977. Imports increased from 11.8 million units in the first quarter of 1977 to 13.6 million units in the first quarter of 1978. The import to domestic production ratio increased from 2.9 percent in 1976 to 15.4 percent in 1977.

Several customers of E & W who were surveyed decreased purchases of jeans from E & W and increased direct and indirect purchases from foreign sources.

E & W of Illmo began importing finished bib overalls in September 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with boys' and men's jeans and overalls produced by E & W of Illmo, Illmo, Mo., contributed importantly to declines in sales and production and to the total or partial separation of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of E & W of Illmo, Illmo, Mo., who became totally or partially separated from employment on or after May 11, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27556 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3804]

ELDER MANUFACTURING CO., McLEANSBORO, ILL.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3804: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 5, 1978, in response to a worker petition received on May 25, 1978, which was filed by the Amalgamated Clothing & Textile Workers Union on behalf of workers and former workers producing men's and boys' dress and sport shirts at the McLeansboro, Ill., plant of Elder Manufacturing Co.

The Notice of Investigation was published in the FEDERAL REGISTER on June 20, 1978 (43 FR 26498). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Elder Manufacturing Co., the U.S. Department of Commerce, the U.S. International Trade Commission, the American Textile Manufacturers Institute, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. The

investigation revealed that all of the criteria have been met.

United States imports of men's and boys' knit dress and sport shirts increased from 74.0 million units in 1976 to 75.2 million units in 1977. Imports increased from 20.0 million units during January-March 1977 to 26.1 million units during January-March 1978.

Imports of men's and boys' woven dress, business, sport, and uniform shirts increased relative to domestic production from 53.9 percent in 1976 to 54.7 percent in 1977. Imports increased from 30.9 million units during January-March 1977, to 34.6 million units during January-March 1978.

Elder Manufacturing Co., imports men's and boys' dress and sport shirts. Company import purchases increased in quantity in 1977 from 1976 and during January-June 1978, compared to January-June 1977. Sales of imported shirts by Elder increased from 4 percent of company sales in 1976 to 34 percent of sales in 1977.

CONCLUSION

After careful review, I concluded that increases of imports of articles like or directly competitive with men's and boys' dress and sport shirts produced by the McLeansboro, Ill., plant of Elder Manufacturing Co., contributed importantly to the declines in production and to the total or partial separations of workers at that plant. In accordance with the provisions of the Trade Act of 1974, I make the following certification:

All workers of the McLeansboro, Ill., plant of Elder Manufacturing Co., who became totally or partially separated from employment on or after May 23, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration and Planning.

[FR Doc. 78-27554 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3708]

EMPRESS HANDBAG CO., INC., NORTH BERGEN, N.J.

Certification Regarding Eligibility To Apply for Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3708: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on May 15, 1978, in response to a worker petition received on May 2, 1978, which was filed by the Pocketbook and Novelty Workers Union, AFL-CIO, on behalf of workers and former workers producing handbags at Empress Handbag Co., Inc., North Bergen, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27923). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Empress Handbag Co., Inc., Jaclyn, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. The investigation revealed that all of the requirements have been met.

U.S. imports of handbags increased in each year from 1975 to 1977. Imports increased from 90.2 million units in 1976 to 92.8 million units in 1977. Imports increased absolutely in the first 3 months of 1978 compared to the first 3 months of 1977.

Empress Handbag Co. imported handbags. Company imports increased from 5.9 percent of sales in 1976 to 13.1 percent of sales in 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with handbags produced at Empress Handbag Co., Inc., North Bergen, N.J., contributed importantly to the decline in production and to the separation of workers at that company. In accordance with the provisions of the Act, I make the following certification:

All workers of Empress Handbag Co., Inc., North Bergen, N.J., who became totally or partially separated from employment on or after April 21, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27555 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3687]

F&P COAT CO., NEPTUNE, N.J.

Certification Regarding eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3687: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on May 8, 1978, in response to a worker petition received on April 28, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing children's coats at F&P Coat Co., Neptune, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of F&P Coat Co., its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met. The investigation has revealed that all of the requirements have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports declined from 590 thousand dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturer for which F&P Coat Co. worked in 1976 and 1977. This manfacturer reduced purchases from F&P Coat Co. and increased purchases of imports in the first quarter of 1978 compared to the first quarter of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the children's coats produced at F&P Coat Co., Neptune, N.J., contributed importantly to the decline in sales and to the separation of workers at that firm. In accordance with the provisions of

the Act, I make the following certification:

All workers of F&P Coat Co., Neptune, N.J., who become totally or partially separated from employment on or after November 1, 1977, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washinton, D.C., this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27557 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2840]

F/V "CAP'N BILL," PROVINCETOWN, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2840: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on January 4, 1978, in response to a worker petition received on December 14, 1977, which was filed on behalf of fishermen and former fishermen catching fish for the F/V *Cap'n Bill*, Provincetown, Mass.

The Notice of Investigation was published in the FEDERAL REGISTER on January 27, 1978 (43 FR 3777). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the F/V *Cap'n Bill*, the U.S. Department of Commerce, the U.S. International Trade Commission, the U.S. Department of the Interior, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The F/V *Cap'n Bill* caught groundfish, flatfish, and scallops. Sales of groundfish, flatfish, and scallops increased in 1976 compared to 1975 and in 1977 compared to 1976. In February 1978, the F/V *Cap'n Bill* sank.

CONCLUSION

After careful review, I determine that all fishermen of the F/V *Cap'n Bill*, Provincetown, Mass. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27558 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-4008]

GENESCO, INC., GENERAL SHOE CO. DIVISION, HUNTSVILLE, ALA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-4008: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on July 31, 1978, in response to worker petition received on July 26, 1976, which was filed on behalf of workers and former workers producing men's footwear at the Huntsville, Ala., plant of the General Shoe Co. Division of Genesco, Inc.

The notice of investigation was published in the FEDERAL REGISTER on August 8, 1978 (43 FR 35130-35131). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the General Shoe Co. Division of Genesco, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of men's dress and casual footwear increased from 47.5 million pairs in 1975 to 58.7 million pairs in 1976 and declined to 56.5 million pairs in 1977, a level still higher than 1975. The ratio of imports to domestic production increased from 70.4 percent in 1976 to 71.7 percent in 1977. Imports increased from 15.7 million pairs in the first 3 months of 1977 to 16.0 million pairs in the first 3 months of 1978. The ratio of imports to domestic production decreased from 77.3 percent in the first 3 months of 1977 to 76.2 percent in the same period of 1978.

U.S. imports of work footwear increased from 2.6 million pairs in 1975 to 4.7 million pairs in 1976 and increased to 5.1 million pairs in 1977. The ratio of imports to domestic production increased from 18.0 percent in 1976 to 20.7 percent in 1977. Imports increased from 0.9 million pairs in the first 3 months of 1977 to 1.7 million pairs in the same period of 1978. The ratio of imports to dometic production increased from 14.3 percent in the first 3 months of 1977 to 2700 percent in the same period of 1978.

Company imports of men's shoes, including work shoes, increased in 1976 compared to 1975, decreased fractionally in 1977 compared to 1976, and then increased in the first 6 months of 1978 compared to the same period of 1977. This increased reliance on foreign sources by General Shoe coincided with declines in production and employment at the Huntsville plant. This increase in company imports of men's shoes during the 1975-78 period is consistent with industry trends, which show that in recent years imports have gained an increased share of both the domestic men's dress and casual footwear market and the domestic work footwear market. While imports of men's dress and casual footwear and imports of work footwear have been increasing, domestic production of these products in general and shipments by General Shoe in particular have been declining. This decline in shipments and the increased use of foreign sources by General Shoe have resulted in numerous plant closings. The closure of General Shoe's Huntsville plant reflects the continued adverse effect of imports on the domestic footwear industry.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports like or directly competitive with the men's footwear produced at the Huntsville, Ala., plant of the General Shoe Co. Division of Genesco, Inc., contributed importantly to the total or partial separation of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of the Huntsville, Ala., plant of the General Shoe Co. Division of Genesco, Inc., who became totally or partially separated from employment on or after June 15, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Plannng.

[FR Doc. 78-27559 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3962]

HEPSUN SPORTSWEAR NEW YORK N.Y.,

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 11, 1978, in response to a worker petition received on June 26, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing slacks and some skirts at Hepsun Sportswear, New York, N.Y.

Notice of investigation was published in the FEDERAL REGISTER on July 25, 1978 (43 FR 32199). No public hearing was requested and none was held.

The petitioner, the International Ladies' Garment Workers' Union, requested withdrawal of this petition. On the basis of the withdrawal continuing the investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 20th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27560 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3118]

HEVEATEX CORP., EVERETT, MASS.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3118: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 13, 1978, in response to a worker petition received on January 26, 1978, which was filed on behalf of workers and former workers producing adhesives and other compounds at Heveatex Corp., Everett, Mass.

The Notice of Investigation was published in the FEDERAL REGISTER on February 28, 1978 (43 FR 8207). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Heveatex Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of adhesives increased in quantity from 4.1 million pounds in 1976 to 7.3 million pounds in 1977, and decreased from 4.2 million pounds in the first quarter of 1977 to 1.1 million pounds in the first quarter of 1978. Imports of adhesives increased in value from $7.4 million in 1976 to $10.2 million in 1977, and increased from $2.4 million in the first quarter of 1977 to $2.8 million in the first quarter of 1978. The ratio of imports to domestic production did not exceed 1.0 percent in the 1973-77 period.

Imports of elastomers (synthetic rubbers) increased in quantity from 269.2 million pounds in 1976 to 361.2 million pounds in 1977, and decreased from 103.3 million pounds in the first quarter of 1977 to 72.7 million pounds in the first quarter of 1978. The ratio of imports to domestic production increased from 5.0 percent in 1976 to 6.3 percent in 1977.

Customers accounting for most of Heveatex's sales in the 1975-77 period were surveyed. These customers who responded purchased no imports, either directly or indirectly from other domestic suppliers. All production at Heveatex was in response to customer orders and according to customer specifications.

Since January, 1, 1978, Heveatex has not engaged in any production, becoming completely a sales operation for the Tillotson Corp., the parent company. Production was transferred, starting gradually throughout the last 6 months of 1977, to another division of Tillotson.

CONCLUSION

After careful review, I determine that the workers of Heveatex Corp., Everett, Mass., are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Ecomomic Research.

[FR Doc. 78-27561 Filed 9-28-78; 8:45 am]

[4510-28]

INVESTIGATIONS REGARDING CERTIFICATIONS OF ELIGIBILITY TO APPLY FOR WORKER ADJUSTMENT ASSISTANCE

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, has instituted investigations pursuant to section 221(a) of the act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the worker's firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the act in accordance with the provisions of Subpart B of 29 CFR Part 90. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

Pursuant to 29 CFR 90.13, the petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 13, 1978.

Interested persons ae invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 13, 1978.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, D.C. 20210.

Signed at Washington, D.C., this 6th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
ASARCO, Inc., Central Research Department (workers).	South Plainfield, N.J	Sept. 5, 1978	Aug. 25, 1978	TA-W-4,136	Conferrous and metallurgical research.
Columbus Coated Fabrics, North Andover Plant (company).	North Andover, Mass	do	Aug. 30, 1978	TA-W-4,137	PVC (poly vinyl chloride) film used in the manufacture of wallcoverings.
Frontier Spar Corp., Bab-Barnes Mine and Mill (International Association of Machinists & Aerospace Workers).	Salem, Ky	do	Aug. 29, 1978	TA-W-4,138	Materials are mined, purified and dried.
Parker Manufacturing Co. (workers)	Worcester, Mass	do	Aug. 22, 1978	TA-W-4,139	Hand tools for Sears.
UFI Razor Blades, Inc. (Distributive Workers of America).	New York, N.Y	Aug. 28, 1978	do	TA-W-4,140	Razor blades.
United Plastic, Inc. (company)	Champaign, Ill	Sept. 5, 1978	Aug. 30, 1978	TA-W-4,141	Disposable polyethylene (plastic) aprons and gloves.

[FR Doc. 78-27583 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3963]

K.A.L. FASHIONS, NEW YORK, N.Y.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 11, 1978 in response to a worker petition received on June 26, 1978, which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing cotton slacks and some skirts at K.A.L. Fashions, New York, N.Y.

Notice of investigation was published in the FEDERAL REGISTER on July 25, 1978 (43 FR 32199). No public hearing was requested and none was held.

The petitioner, the International Ladies' Garment Workers' Union, requested withdrawal of this petition. On the basis of the withdrawal continuing the investigation would serve no purpose. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 20th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27562 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3449]

LAFOLLETTE SHIRT DIVISION, IMPERIAL READING CORP., LAFOLLETTE, TENN.

Determinations Regarding Eligibility To Apply for Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3449: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 30, 1978, in response to a worker petition received on March 13, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing men's dress and sport shirts at the LaFollette Shirt Division of the Imperial Reading Corp., LaFollette, Tenn. During the course of the investigation it was determined that denim products were also produced at the plant.

The Notice of Investigation was published in the FEDERAL REGISTER on April 25, 1978 (43 FR 17551). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of the Imperial Reading Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. With respect to workers producing men's dress and sport shirts it is concluded that all of the requirements have been met.

U.S. imports of men's and boys' woven dress, business, sport, and uniform shirts increased from 91,808 thousand units in 1975 to 144,103 thousand units in 1976. Imports then decreased to 139,720 thousand units in 1977. Imports increased from 30,875 thousand units in the first quarter of 1977 to 34,583 thousand units for the same period of 1978. The imports to domestic production ratio increased from 36.8 percent in 1975 to 53.9 percent in 1976, and then to 54.7 percent in 1977.

A survey of major customers of the LaFollette Shirt Division of the Imperial Reading Corp. indicated that many of those customers which had decreased purchases of shirts from Imperial, in 1977 or in the first quarter of 1978, had increased purchases of imports, either directly or from other domestic sources, during the same period.

With respect to workers producing denim products, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

The Department's investigation revealed that production of denim products at the LaFollette Shirt Division of the Imperial Reading Corp., LaFollette, Tenn., increased from 1976 to 1977 and in the first quarter of 1978 compared to the same period in 1977. Sales and production are approximately equal at the LaFollette plant.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with men's dress and sport shirts produced at the LaFollette Shirt Division of the Imperial Reading Corp., LaFollette, Tenn., contributed importantly to the decline in sales and production of that product and to the total or partial separation of workers producing that product at the plant. In accordance with the provisions of the act, I make the following certification:

All workers of the LaFollette Shirt Division of the Imperial Reading Corp., LaFollette, Tenn., engaged in employment related to the production of men's dress and sport shirts, who became totally or partially separated from employment on or after March 1, 1977, and before March 5, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974. Workers separated on or after March 5, 1978, are denied eligibility.

I further determine that workers engaged in employment related to the production of denim products are denied eligibility to apply for adjustment assistance.

Signed at Washington, D.C., this 21st day of September 1978.

HARRY J. GILMAN,
Acting Director, Office Foreign Economic Research.

[FR Doc. 78-27563 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3596]

LAMAR COAT, INC., PATERSON, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3596: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' and children's coats, at Lamar Coat, Inc., Paterson, N.J. The investigation revealed that the firm did not produce children's coats in 1976 and 1977.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Lamar Coat, Inc., its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports declined from 590 thousand dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturers for which Lamar Coat, Inc., worked in 1976 and 1977. Manufacturers that accounted for a majority of sales in 1976 reported that they reduced purchases from Lamar Coat, Inc. and increased purchases of imported ladies' coats in 1977 compared to 1976. Lamar Coat, Inc., closed permanently in the beginning of January 1978.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' coats produced at Lamar Coat, Inc., Paterson, N.J. contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the Act, I make the following certification:

All workers of Lamar Coat, Inc., Paterson, N.J. who became totally or partially separated from employment on or after November 1, 1977 are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27564 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3711]

LEEDS TRAVELWEAR CLAYTON, DEL.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3711: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 15, 1978 in response to a worker petition received on May 2, 1978 which was filed by the Luggage Workers Union on behalf of workers and former workers producing luggage and luggage accessories and golf bags, bowling bags, and tennis bags at Leeds Travel Wear, Clayton, Del.

The investigation revealed that the company name is Leeds Travelwear, and the formal name of the union is the International Leather Goods, Plastic and Novelty Workers' Union. Leeds no longer produces tennis bags. In addition to the workers at the Clayton, Del. plant, the company employs three luggage salespersons who work out of their respective residences in Irvine, Calif., Chicago, Ill., and North Chicago, Ill.

The Notice of Investigation was published in the FEDERAL REGISTER on June 27, 1978 (43 FR 27923). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Leeds Travelwear, its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The investigation has revealed that all of the requirements have been met.

Imports of luggage, which includes sports bags, increased in value from $112.5 million in 1976 to $137.7 million in 1977, and increased from $28.9 million in the first quarter of 1977 to $42.1 million in the first quarter of 1978. The ratio of imports to domestic production increased from 24.7 percent in 1976 to 28.4 percent in 1977, and increased from 23.8 percent in the first quarter of 1977 to 32.4 percent in the first quarter of 1978.

There were no company imports of luggage in 1977. In February 1978, Leeds Travelwear began a luggage import program. Imports of luggage in the February-May period of 1978 represented 29 percent of company sales in value for that period. The luggage is produced on a contractual basis in Taiwan. Leeds does not import sports bags of any kind.

Most of the customers who purchase luggage from Leeds who responded to the Department's survey reported purchasing some imported luggage. Some of these customers increased imports and reduced purchases from Leeds in 1977 compared to 1976 and/or in the first quarter of 1978 compared to the first quarter of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases of imports of articles like or directly competitive with luggage produced by Leeds Travelwear, Clayton, Del., contributed importantly to the decline in sales or production and to the total or partial separation of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers of the Clayton, Del. plant and workers in Irvine, Calif., North Chicago, Ill., and Chicago, Ill. of Leeds travelwear, who became totally or partially separated from employment on or after April 11, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22nd day of September 1978.

GLORIA G. PRATT
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27565 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3183]

LEFETON CUSTOM TAILORING, INC., NEW YORK, N.Y.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3183: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 21, 1978, in response to a worker petition received on February 6, 1978, which was filed by the Amalgamated Clothing and Textile Workers' Union on behalf of workers and former workers producing men's and boys' tailored clothing at Lefeton Custom Tailoring, Inc., New York, N.Y. During the course of the investigation, it was established that the firm produces men's tailored suitcoats, and men's and women's tailored sportcoats.

The Notice of Investigation was published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8864). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Lefeton Custom Tailoring, Inc., the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That sales or production, or both, of the firm or subdivision have decreased absolutely.

On January 17, 1976, the employees of Lefeton Custom Tailoring, Inc., were certified as eligible to apply for trade adjustment assistance (TA-W-296). That certification expired on January 17, 1978.

Evidence developed during the course of the investigation showed that production of suitcoats and sportcoats at Lefeton Custom Tailoring increased by 42.8 percent in quantity and by 88.3 percent in value during the first half of 1978, as compared to the first half of 1977. Production for each month from March through June of 1978 was higher than the corresponding month of the same period in 1977. Sales and production are equal at Lefeton Custom Tailoring.

CONCLUSION

After careful review, I determine that all workers at Lefeton Custom Tailoring, Inc., New York, N.Y. are denied eligibility to apply for trade adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27566 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3690]

M & D SHOP, INC., SUMMIT, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3690: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' toppers, coats and raincoats at M & D Shop, Summit, N.J. The Department's investigation revealed that the correct name of the company was M & D Shop, Inc.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of M & D Shop, Inc. its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The Department's investigation revealed that all of the criteria have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252 thousand dozen in 1976 to 2,752 thousand dozen in 1977. Imports declined from 590 thousand dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturer for which M & D Shop, Inc. worked in 1976 and 1977. The manufacturer that accounted for 100 percent of sales in 1976 reported that it had increased purchases from M & D Shop Inc. and increased purchases of imported ladies' coats in 1977 compared to 1976. The manufacturer increased imports of ladies' coats in the first quarter of 1978 compared to the first quarter of 1977. M & D Shop ceased production permanently in November, 1977 because of lack of orders.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' toppers, coats and raincoats, produced at M & D Shop, Inc., Summit, N.J. contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of M & D Shop, Inc., Summit, N.J. who became totally or partially separated from employment on or after October 22, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22d day of September 1978.

GLORIA G. PRATT,
Director, Office of Foreign Economic Policy.

[FR Doc. 78-27568 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3881]

MADISON WIRE CO., WEST SENECA, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3881: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on June 22, 1978 in response to a worker petition received on June 21, 1978 which was filed on behalf of workers and former workers producing steel wire and wire products at the Madison Wire Co., West Seneca, N.Y.

The Notice of Investigation was published in the FEDERAL REGISTER on June 30, 1978 (43 FR 28579). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Madison Wire Co., the U.S. Department of Commerce, the U.S. International Trade Commission, the American Iron and Steel Institute, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

U.S. imports of carbon steel wire increased from 349.6 thousand short tons in 1975 to 371.8 thousand short tons in 1976 and to 470.5 thousand short tons in 1977. Imports increased from 112.5 thousand short tons in the first 3 months of 1977 to 138.9 thousand short tons in the first 3 months of 1978. The ratio of imports to domestic shipments increased from 19.9 percent in 1976 to 25.5 percent in 1977 and increased from 25.0 percent in the first 3 months of 1977 to 28.8 percent in the first 3 months of 1978.

U.S. imports of stainless steel wire increased from 19.4 thousand short tons in 1975 to 20.8 thousand short tons in 1976 and to 30.1 thousand short tons in 1977. Imports increased from 7.3 thousand short tons in the first 3 months of 1977 to 8.8 thousand short tons in the first 3 months of 1978. The ratio of imports to domestic shipments increased from 35.9 percent in 1976 to 51.1 percent in 1977.

A survey of Madison Wire's customers was conducted by the Department of Commerce. The firms surveyed accounted for most of the subject firm's sales loss from 1976 to 1977. These firms indicated they had decreased purchases from Madison Wire Company and increased purchases of imported steel wire.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with stainless steel wire and carbon steel wire and wire products produced at Madison Wire Co., West Seneca, N.Y., contributed importantly to the decline in sales and production and to the total or partial separation of workers of that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Madison Wire Co., West Seneca, N.Y. who became totally or partially separated from employment on or after January 29, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22nd day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management. Administration and Planning.

[FR Doc. 78-27567 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3750]

MCGREGOR-DONIGER, INC. BERWICK, PA.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3750: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 23, 1978 in response to a worker petition received on May 15, 1978 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers engaged in the distribution of men's outer coats and jackets at the Berwick, Pa. distribution center of McGregor-Doniger, Inc.

The notice of investigation was published in the FEDERAL REGISTER on June 6, 1978 (43 FR 24633). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of McGregor-Doniger, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department's investigation revealed that the petition was filed on behalf of workers and former workers at the Berwick, Pa. distribution center of McGregor-Doniger, Inc. This distribution center received, warehoused and shipped men's outer garments exclusively for McGregor-Doniger, Inc. Pursuant to a related investigation (TA-W-2387, Notice of Determination issued April 7, 1978), workers at the Dover, N.J. plant of McGregor-Doniger, Inc. were denied eligibility to apply for trade adjustment assistance on the grounds that increased imports of men's outer coats and jackets did not contribute importantly to the separation of workers and to the decline in sales and production at that plant.

Since the Berwick, Pa. distribution center handles the products of McGregor-Doniger, Inc. exclusively, it follows that increased imports could not have contributed importantly to the separation of workers at the distribution center.

CONCLUSION

After careful review I determine that all workers of the Berwick, Pa. distribution center of McGregor-Doniger, Inc. are denied eligibility to apply for trade adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 20th day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27569 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3035 & TA-W-3036]

NELSON KNITTING MILLS, NORTH SHORE MANUFACTURING CO., DULUTH, MINN.

Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3035 and TA-W-3036: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on February 6, 1978 in response to a worker petition received on January 9, 1978, which was filed on behalf of workers and former workers producing knit trim, men's and boys' wool sweaters and men's and boys' leather-and-wool jackets at Nelson Knitting Mills and workers producing infant sleepers and snowmobile suits at North Shore Manufacturing Co., Inc. Duluth, Minn.

The notice of investigation was published in the FEDERAL REGISTER on February 17, 1978 (42 FR 7064). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Davenshire, Inc., the parent company, its customers, the National Cotton Council of America, the American Textile Manufacturers Association, the National Knitted Outerwear Association, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group of eligibility requirements of section 222 of the Trade Act of 1974 must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

> That increases of imports of articles like or directly competitive with articles produced by the firm or subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

A survey of the customers of North Shore Manufacturing revealed that none of the customers reported purchasing imports of snowmobile suits or infant sleepers.

Half of the sales by Nelson Knitting Mills in 1976 and 1977 consisted of knit trim for infant sleepers and snowmobile suits for its affiliate, North Shore Manufacturing which does not import knit trim or finished garments. A survey of the customers of Nelson Knitting Mills revealed that none of the customers reported purchasing imports of men's and boys' jackets and only one customer, representing an insignificant proportion of the subject firm's sales, indicated purchases of imported men's wool sweaters.

CONCLUSION

After careful review I determine that all workers of Nelson Knitting Mills and North Shore Manufacturing, Duluth, Minn. are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 22nd day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27570 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3151, 3343]

NICE BEARING DIVISION OF SKF INDUSTRIES, INC., KULPSVILLE AND PHILADELPHIA, PA.

Negative Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3151, 3343: Investigations regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigations were initiated on February 16, 1978, and March 9, 1978, in response to a worker petition received on February 6, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing ball bearings at the Nice Bearing Division of SKF Industries, Inc., Kulpsville and Philadelphia, Pa.

The notices of investigation were published in the FEDERAL REGISTER on March 3, 1978 (43 FR 8862), and March 24, 1978 (43 FR 12401). No public hearing was requested and none was held.

The information upon which the determinations were made was obtained principally from officials on the Nice Bearing Division of SKF Industries, Inc., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. Without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

A survey of customers of the Nice Bearing Division of SKF Industries revealed that the majority of customers surveyed did not purchase imported ball bearings, like or directly competitive with those produced by the Nice Division during the 1975–June 1978 period. Most of the customers surveyed that reduced purchases from the Nice Division shifted purchases to other domestic sources.

CONCLUSION

After careful review I determine that all workers at the Nice Bearing Division of SKF Industries, Inc., Kulpsville and Philadelphia, Pa. are denied eligibility to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management, Administration, and Planning.

[FR Doc. 78-27571 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3371]

ROCHESTER CLOTHING CORP., ROCHESTER, N.Y.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3371: Investigation regarding eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on March 30, 1978, in response to a worker petition received on February 21, 1978, which was filed by the Amalgamated Clothing & Textile Workers' Union on behalf of workers and former workers producing men's suits, sports coats, and slacks at the Rochester Clothing Corp., Rochester, N.Y. The petition is expanded to include employees in the Rochester Clothing Corp.'s sales office at 1290 Avenue of the Americas, New York, N.Y., engaged in employment related to the sale of men's suits, sports coats, and jackets produced at the Rochester Clothing Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on April 7, 1978 (43 FR 14776). No public hearing was requested, and none was held.

The information upon which the determination was made was obtained principally from officials of the Rochester Clothing Corp., its customers, the U.S. Department of Commerce, the United States International Trade Commission, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the Trade Act of 1974 must be met. The investigation has revealed that all of the requirements have been met.

Imports of men's and boys' tailored suits increased from 3,106,000 units in 1975 to 3,562,000 units in 1976, increased to 4,091,000 units in 1977. The ratio of imports to domestic production increased from 19.0 percent in 1975 to 20.0 percent in 1977.

Rochester Clothing Corp. decreased its business with its major customer from 1976 to 1977 and in the first quarter of 1978 compared to the first quarter of 1977. That customer, which marketed its apparel directly to consumers, decreased its business over the same periods of time. Major retailers with stores in markets served by Bond clothing stores have sharply inreased imports of men's and boys' suits and sports coats.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases in imports of articles like or directly competitive with men's suits, sports coats, and slacks produced at the Rochester Clothing Corp., Rochester, N.Y., contributed importantly to the decrease in sales or production and to the total or partial separations of workers at that firm. In accordance with the provisions of the act, I make the following certification:

All workers of the Rochester Clothing Corp., at the Rochester, N.Y., plant and in the 1290 Avenue of the Americas, New York, N.Y., sales office engaged in employment related to the production of men's suits, sport coats, and jackets who became totally or partially separated from employment on or after March 18, 1978, are eligible to apply for adjustment assistance under title II, chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 22d day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27572 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3455]

ST. JOE ZINC CO., SMELTING DIVISION, MONACA, PA.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974, the Department of Labor herein presents the results of TA-W-3455: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on March 30, 1978 in response to a worker petition received on March 13, 1978, which was filed by the United Steel Workers of America, on behalf of workers mining zinc metal and zinc oxide at the Josephtown Smelter, Monaca, Pa.

The investigation revealed that workers at St. Joe Zinc Co., Zinc Smelting Division were producing zinc oxide, slab zinc, and various sub-products.

The notice of investigation was published in the FEDERAL REGISTER on April 25, 1978 (43 FR 17551). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials at St. Joe Zinc Co., the U.S. Department of Commerce, the U.S. Department of Interior *Metals Week and Metals Bulletin*, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of section 222 of the act must be met. It is concluded that all of the requirements have been met.

St. Joe Zinc Co.'s Smelter at Monaca, Pa., produces slab zinc, zinc oxide, and the following by-products, sulphuric acid, cadnium, ferrosilicon, lead cake and zinc dust, using zinc concentrates from their own zinc mines in Missouri and imports from Canada.

Imports of slab zinc increased absolutely from 1975 to 1976 and decreased from 1976 to 1977. The ratios of imports to domestic production and domestic consumption, increased from 1975 to 1976 and from 1976 to 1977. The ratio of imports to domestic production has been for the last 2 years, above the one hundred mark, while the ratio of imports to domestic consumption has been above the 50 percent mark. In 1968 the ratio of imports to domestic production was 28.30 percent and in 1977 had increased to 127.90 percent.

The industry sources maintain that domestic suppliers of zinc can remain competitive with foreign suppliers as long as the domestic price is within 5 cents per pound of the London Metal Exchange price. Except for brief periods in the spring and summer of 1976 and in March 1977, the price differential between U.S. producers and the LME has exceeded 5 cents per pound. The average U.S. producers price of zinc was 7.6 cents per pound higher than the average LME zinc price in 1977, well above the 5 cents limit at which domestic suppliers can remain competitive.

Evidence developed during the course of the investigation indicates that imports of slab zinc metal have been an important factor affecting domestic sales of zinc and depressing the price of zinc. The depressed prices of zinc brought about a reduction in the domestic production of refined zinc and has resulted in cutbacks and shutdowns at many mines, concentrators and smelters, among them the Josephtown Smelter in Monaca, Pa.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases of imports of articles like or directly competitive with the slab zinc produced at the Josephtown Smelter of the St. Zinc Co., Monaca, Pa., contributed importantly to the decline in production and to the partial or total separation of workers at the Smelter. In accordance with the provisions of the act. I make the following certification:

All workers at the Josephtown Smelter of the St. Joe Zinc Co., Monaca, Pa. who became totally or partially separated from employment on or after July 1, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27574 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3609]

STAR FASHION COAT CO., PATERSON, N.J.

Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-3609: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on May 8, 1978 in response to a worker petition received on April 28, 1978 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats, overcoats, and blazers at Star Fashion Coat Co., Paterson, N.J.

The Notice of Investigation was published in the FEDERAL REGISTER on May 26, 1978 (43 FR 22793). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from officials of Star Fashion Coat Co., its customers (manufacturers), the U.S. Department of Commerce, the U.S. International Trade Commission, the National Cotton Council of America, industry analysts, and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met. The Department's investigation revealed that all of the requirements have been met.

U.S. imports of women's, misses', and children's coats and jackets increased from 2,252 thousand dozen in 1976 to 2,723 thousand dozen in 1977. Imports declined from 590 thousand dozen in the first quarter of 1977 to 572 thousand dozen in the first quarter of 1978. The ratio of imports to domestic production increased from 48.3 percent in 1976 to 54.9 percent in 1977.

The Department conducted a survey of the principal manufacturers for which Star Fashions worked in 1976 and 1977. Manufacturers that accounted for a majority of sales in 1976 reported that they increased purchases from Star Fashions and reduced purchases of imported ladies' coats, overcoats, and blazers in 1977 compared to 1976. Manufacturers that accounted for a majority of sales in 1977 reported that they reduced purchases from Star Fashions and increased pruchases of imports in the first quarter of 1978 compared to the first quarter of 1977.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increased imports of articles like or directly competitive with the ladies' coats, overcoats, and blazers produced at Star Fashion Co., Paterson, N.J. contributed importantly to the decline in sales and to the separation of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of Star Fashion Coat Co., Paterson, N.J., who became totally or partially separated from employment on or after November 1, 1977 are eligible to apply for a

justment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 20th day of September 1978.

HARRY J. GILMAN,
Acting Director, Office of Foreign Economic Research.

[FR Doc. 78-27573 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-2837]

UNION CARBIDE CORP. METALS DIVISION ALLOY, W.VA.

Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 the Department of Labor herein presents the results of TA-W-2837: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the act.

The investigation was initiated on January 3, 1978 in response to a worker petition received on December 21, 1977, which was filed on behalf of workers and former workers producing silicon metal, ferrosilicon, special silicon, silicomanganese, ferromanganese silicon, and medium carbon and low carbon ferromanganese at the Alloy, West Virginia Metals Division plant of Union Carbide Corp.

The Notice of Investigation was published in the FEDERAL REGISTER on January 17, 1978 (43 FR 2459). No public hearing was requested and none was held.

The information upon which the determination was made was obtained principally from Union Carbide Corp., its customers, the U.S. Department of Commerce, the U.S. International Trade Commission, industry analysts and Department files.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the act must be met.

With respect to workers producing medium carbon and low carbon ferromanganese, without regard to whether any of the other criteria have been met, the following criterion has not been met.

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threats thereof, and to the absolute decline in sales or production.

Imports of medium and low carbon ferromanganese increased in 1976 from 1975, decreased 25 percent in 1977 from 1976 from 1975 and decreased 28 percent in the first quarter of 1978 compared to the first quarter of 1977. The ratio of imports to domestic production decreased from 80.0 in 1976 to 67.5 in 1977.

With respect to workers producing ferrochrome silicon, silicomanganese, ferromanganese silicon, silicon metal and ferrosilicon, all of the group eligibility requirements of section 222 of the act have been met.

Ferrochrome Silicon-FeCrSi

Imports of FeCrSi increased 280 percent in 1976 from 1975, increased 3 percent in 1977 from 1976. The ratio of imports to domestic production increased from 28.4 percent in 1976 to 30.6 percent in 1977.

Production and sales of FeCrSi at the plant increased in quantity in 1976 and decreased in 1977 from 1976.

Customers of Union Carbide decreased purchases of FeCrSi from Union Carbide and increased purchases of imports in 1977 from 1976.

Silicomanganese-SiMn-and Ferromanganese Silicon-FeMnSi

Imports of FeMnSi are included in the statistics for SiMn so the two products are combined.

Imports of SiMn increased 44 percent in quantity in 1976 from 1975 and increased 10 percent in 1977 from 1976. The ratio of imports to domestic production increased 45.5 percent in 1976 to 54.3 percent in 1977.

Production and sales of SiMn and FeMnSi at the plant decreased in quantity in 1976 from 1975 and decreased in 1977 from 1976.

Union Carbide increased imports of SiMn and FeMnSi in 1978 from 1977.

Silicon Metal

Imports of silicon metal increased 40 percent in 1976 from 1975 and increased 181 percent in 1977 from 1976. The ratio of imports to domestic production increased from 6.7 percent in 1976 to 21.8 percent in 1977.

Production of silicon metal at the plant increased in quantity in 1976 from 1975 and decreased in 1977 from 1976.

Customers of Union Carbide decreased purchases of silicon metal from Union Carbide and increased purchases of imports in 1977.

Ferrosilicon-FeSi

Imports of FeSi increased 40 percent in 1976 from 1975 and increased 16 percent in 1977 from 1976. The ratio of imports to domestic production increased from 15.3 percent in 1976 to 18.1 percent in 1977.

Production of FeSi at the plant decreased in quantity in 1976 from 1975 and decreased in 1977 from 1976.

Customers of Union Carbide decreased purchases of FeSi from Union Carbide and increased purchases of imports in 1977.

Total production at the plant decreased in 1976 from 1975 and total sales and production decreased in 1977 from 1976.

Average production employment at the plant decreased in 1976 from 1975 and decreased in 1977 from 1976. Employees at the plant are not separately identifiable by product.

CONCLUSION

After careful review of the facts obtained in the investigation I conclude that increases in imports of articles like or directly competitive with ferrochrome silicon, silicomanganese, ferromanganese silicon, silicon metal, and ferrosilicon produced at the Alloy, West Virginia Metals Division plant of Union Carbide Corp. contributed importantly to the decline in sales and production and to the total or partial separations of workers at that plant. In accordance with the provisions of the act, I make the following certification:

All workers of the Alloy, West Virginia Metals Division plant of Union Carbide Corp. who are engaged in employment related to the production of ferrochrome silicon, silicomanganese, ferromanganese silicon, silicon metal and ferrosilicon who became totally or partially separated from employment on or after December 21, 1976, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further conclude that workers of the Alloy, West Virginia Metals Division plant of Union Carbide Corp. who are engaged solely in employment related to production of any products not specifically mentioned above are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 21st day of September 1978.

JAMES F. TAYLOR,
Director, Office of Management Administration and Planning.

[FR Doc. 78-27575 Filed 9-28-78; 8:45 am]

[TA-W-3950]

WUNDIES, INC., WELLSBORO, PA.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 5, 1978 in response to a worker petition received on July 5, 1978 which was filed on behalf of workers and former workers producing children's underwear and sleepwear and ladies' underwear at the Wellsboro, Pa., plant of Wundies, Inc.

Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-30929). No public hearing was requested and none was held.

The petitioner, Wundies, Inc., requested withdrawal of such petition. The basis for the withdrawal is that no significant separations of workers have yet occurred. The effect of imports on the production at domestic plants of Wundies, Incorporated is not expected for more than a year from the date of the petitions' submission. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 13th day of September, 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27576 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3949]

WUNDIES, INC. LIBERTY, PA.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 5, 1978 in response to a worker petition received on July 5, 1978 which was filed on behalf of workers and former workers producing children's underwear and sleepwear and ladies' underwear at the Liberty, Pa. plant of Wundies. Inc.

Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-30929). No public hearing was requested and none was held.

The petitioner, Wundies, Inc., requested withdrawal of such petition. The basis for the withdrawal is that no significant separations of workers have yet occurred. The effect of imports on the production at domestic plants of Wundies, Inc. is not expected for more than a year from the date of the petitions' submission. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 13th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27577 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3948]

WUNDIES, INC., WILLIAMSPORT, PA.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was initiated on July 5, 1978 in response to a worker petition received on July 5, 1978 which was filed on behalf of workers and former workers producing children's underwear and sleepwear and ladies' underwear at the Williamsport, Pa. plant of Wundies, Inc.

Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-30929). No public hearing was requested and none was held.

The petitioner, Wundies, Inc., requested withdrawal of such petition. The basis for the withdrawal is that no significant separations of workers have yet occurred. The effect of imports on the production at domestic plants of Wundies, Inc. is not expected for more than a year from the date of the petitions' submission. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 13th day of September 1978.

MARVIN M. FOOKS,
Director Office of Trade Adjustment Assistance.

[FR Doc. 78-27578 Filed 9-28-78; 8:45 am]

[4510-28]

[TA-W-3947]

WUNDIES, INC., NEW YORK, N.Y.

Termination of Investigation

Pursuant to section 221 of the Trade Act of 1974, an investigation was intitated on July 5, 1978, in response to a worker petition received on July 5, 1978, which was filed on behalf of workers and former workers at the sales office of Wundies, Inc. located in New York, N.Y.

Notice of Investigation was published in the FEDERAL REGISTER on July 18, 1978 (43 FR 30928-30929). No public hearing was requested and none was held.

The petitioner, Wundies, Inc. requested withdrawal of such petition. The basis for the withdrawal is that no significant separations of workers have yet occurred. The effect of imports on the production at domestic plants of Wundies, Inc. is not expected for more than a year from the date of the petitions' submission. Consequently, the investigation has been terminated.

Signed at Washington, D.C., this 13th day of September 1978.

MARVIN M. FOOKS,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 78-27579 Filed 9-28-78; 8:45 am]

[6820-35]

LEGAL SERVICES CORPORATION

MICHIGAN MIGRANT LEGAL SERVICES, BERRIEN SPRINGS, MICH.

Grants and Contracts

SEPTEMBER 22, 1978.

The Legal Services Corp. was established pursuant to the Legal Services Corporation Act of 1974, Pub. L. 93-355, 88 Stat. 378, 42 U.S.C. 2996-2996*l*, as amended, Pub. L. 95-222 (December 28, 1977). Section 1007(f) provides: "At least 30 days prior to the approval of any grant application or prior to entering into a contract or prior to the initiation of any other project, the corporation shall announce publicly * * * such grant, contract or project."

The Legal Services Corp. hereby announces publicly that it is considering the grant application submitted by:

Michigan Migrant Legal Services in Berrien Springs, Mich. to serve the Native Americans in Michigan.

Interested persons are hereby invited to submit written comments or recommendations concerning the above application to the Regional Office of the Legal Services Corp. at:

Legal Services Corp., Denver Regional Office, 1726 Champa Street, Suite 500, Denver, Colo. 80202.

THOMAS EHRLICH,
President.

[FR Doc. 78-27491 Filed 9-28-78; 8:45 am]

[7536-01]

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

ADVISORY COMMITTEE; HUMANITIES PANEL

Meeting

SEPTEMBER 25, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended), notice is hereby given that a meeting of the Humanities Panel will be held at 806 15th Street NW., Washington, D.C. 20506, in the 11th floor conference room from 9 a.m. to 5:30 p.m. on October 17, 1978.

The purpose of the meeting is to review State, local, and regional history applications submitted to the general research program of the National Endowment for the Humanities, for projects beginning March 1, 1979.

Because the proposed meeting will consider financial information and disclose information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, pursuant to authority granted me by the Chairman's delegation of authority to close advisory committee meetings, dated January

15, 1978, I have determined that the meeting would fall within exemptions (4) and (6) of the 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street NW., Washington, D.C. 20506, or call area code 202-724-0367.

STEPHEN J. MCCLEARY,
Advisory Committee Management Officer.

[FR Doc. 78-27492 Filed 9-28-78; 8:45 am]

[3110-01]

OFFICE OF MANAGEMENT AND BUDGET

CLEARANCE OF REQUESTS

List of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public received by the Office of Management and Budget on September 25, 1978 (44 U.S.C. 3509). The purpose of publishing this list in the FEDERAL REGISTER is to inform the public.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; an indication of who will be the respondents to the proposed collection; the estimated number of responses; the estimated burden in reporting hours; and the name of the reviewer or reviewing division or office.

Requests for extension which appear to raise no significant issues are to be approved after brief notice through this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, 202-395-4529, or from the reviewer listed.

NEW FORMS

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Recordkeeping requirements, on occasion, recordkeeping requirements, Laverne V. Collins, 395-3214.

DEPARTMENT OF DEFENSE

Departmental and Other Reserve Component Attitude Study, single time, youth, 4,500 responses, 2,250 hours, Office of Federal Statistical Policy and Standard, Marsha Traynham, 673-7956.

DEPARTMENT OF LABOR

Bureau of Labor Statistics, OOQ Subscriber Survey, 3110, single time, job/career counselors, 1,400 responses, 117 hours, Strasser, A., 395-6132.

REVISIONS

VETERANS ADMINISTRATION

Veterans Application for Compensation and Pension, 21-526, on occasion, veterans, 250,000 responses, 250,000 hours, Caywood, D. P., 395-3443.

Statement of Income and Net Worth—Disability, 21-6897, on occasion, veteran, 200,000 responses, 100,000 hours, Caywood, D. P., 395-3443.

DEPARTMENT OF COMMERCE

Maritime Administration, Application for Transfer of Vessels, MA-29, 29A, and 29B, on occasion, shipowner, 100 responses, 650 hours, C. Louis Kincannon, 395-3211.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Center for Disease Control, National Disease Surveillance—I. Case reports, on occasion, State and territorial health departments, 33,919 responses, 16,477 hours, Office of Federal Statistical Policy and Standard, 673-7956.

DEPARTMENT OF JUSTICE

Law Enforcement Assistance Administration, Summary of Sentenced Population Movement, NPS-1 (LEAA SER. 3620), annually, State correction agencies, 60 responses, 120 hours, Office of Federal Statistical Policy and Standard, 673-7956.

DEPARTMENT OF LABOR

Employment and Training Administration:
- Job Order Form, ES-514, on occasion, employers using ES services, 3,960,000 responses, 396,000 hours, Strasser, A., 395-6132.
- Application Card; Applicant/Job Order Transaction, ES-511 and ES-516, on occasion, job seekers applying at State ES offices, 15,167,000 responses, 3,856,500 hours, Strasser, A., 395-6132.

Bureau of Labor Statistics, Director of National Unions and Employee Associations, BLS-2441, 2441-A, and 2441-B, single time, labor organizations, 450 responses, 675 hours, Office of Federal Statistical Policy and Standard, 673-7956.

EXTENSIONS

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Alcohol, Drug Abuse, and Mental Health Administration, Alcoholism Treatment Center Questionnaire, quarterly, communities' awareness of alcohol treatment centers, 314,000 responses, 25,300 hours, Richard Eisinger, 395-3214.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service:
- Application for Removal From the United States, I-243, on occasion, applicants for removal from the United States, 200 responses, 33 hours, Laverne V. Collins, 395-3214.
- Application for waiver of the Foreign Residence Requirement, I-612, on occasion, aliens subject to section 212(e) of the act, 1,000 responses, 330 hours, Laverne V. Collins, 395-3214.

DEPARTMENT OF LABOR

Employment and Training Administration:
- Indicators of Compliance (migrant worker services), ETA-5-148A-E, monthly, State ES agencies, 624 responses, 18,720 hours, Strasser, A., 395-6132.

Bureau of Labor Statistics, Information for the Producer Price Index Telephone, Communication Price Indexes SIC 4811, BLS-473, 473A, and 473E, monthly, manufacturers and producers companies in SIC 4811, 108,420 responses, 18,140 hours, Strasser, A., 395-6132.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration, Operations Specifications (for air carriers), FAA-1014, on occasion, air carriers, 6,800 responses, 1,700 hours, Strasser, A., 395-6132.

DAVID R. LEUTHOLD,
Budget and Management Officer.

[FR Doc. 78-27676 Filed 9-28-78; 8:45 am]

[8010-01]

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-15126; File No. SR-Amex-78-17]

AMERICAN STOCK EXCHANGE, INC.

Self-Regulatory Organization; Proposed rule change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78s(b)(1), as amended by Pub. L. 94-29, 16 (June 4, 1975), notice is hereby given that on August 21, 1978, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change. The American Stock Exchange, Inc. ("Amex") has provided the Commission with the following statement of terms of substance, purpose, and basis under the Act of the proposed rule change.

STATEMENT OF TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The proposed amendment to Amex rule 6 will broaden the scope of permissible off-board agency transactions in listed bonds to that set forth in rule 19c-1 (17 CFR 240.19c-1) under the Act for equity securities. Rule 19c-1 prescribes restrictions on off-board agency transactions, except in-house agency cross transactions.

PURPOSE OF THE PROPOSED RULE CHANGE

The purpose of the proposed rule change is to eliminate restrictions on off-board agency transactions in listed bonds (other than in-house agency cross transactions) which the Amex has determined are no longer necessary or appropriate.

BASIS UNDER THE ACT

The amendment to Amex rule 6 is designed to remove impediments to a free and open market and to eliminate any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, and therefore is authorized by subparagraphs (b)(5) and (b)(8) of section 6 of the Act.

COMMENTS RECEIVED FROM MEMBERS, PARTICIPANTS, OR OTHERS ON PROPOSED RULE CHANGE

Amex states that no comments were solicited or received with respect to the proposed rule change.

BURDEN ON COMPETITION

The Amex has determined that no burden on competition will be imposed by the proposed rule change.

On or before November 3, 1978, or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions should file six (6) copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 20, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 1, 1978.

[FR Doc. 78-27432 Filed 9-28-78 8:45 am]

[8010-01]

[Release No. 34-15174; File No. SR-BSE-78-9]

BOSTON STOCK EXCHANGE, INC.

Self-Regulatory Organization; Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. 94-29, 16 (June 4, 1975), notice is hereby given that on September 11, 1978, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed change as follows:

BSE'S STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

"That the annual membership dues be increased from $1,000 to $1,200 effective October 1, 1978."

BSE'S STATEMENT OF BASIS AND PURPOSE

PURPOSE OF THE PROPOSED CHANGE

The purpose of the proposed change is to increase the annual membership dues from $1,000 to $1,200.

BASIS OF THE PROPOSED CHANGE

The basis under the Act for the proposed change is section 6(b)(4) and provides for the equitable allocation of reasonable dues among the members of the exchange.

COMMENTS RECEIVED FROM MEMBERS, PARTICIPANTS, OR OTHERS ON PROPOSED CHANGE

No comments were solicited or received.

BSE'S STATEMENT OF BURDEN ON COMPETITION

No burden on competition is perceived by adoption of the proposed increase in membership dues.

The foregoing change has become effective pursuant to section 19(b)(3) of the Securities Exchange Act of 1934. At any time within 60 days of filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purpose of the Securities Exchange Act of 1934.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 20, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 19, 1978.

[FR Doc. 70-27433 Filed 9-28-78; 8:45 am]

[8010-01]

[Release No. 34-15180; File No. SR-DTC-78-12]

DEPOSITORY TRUST CO.

Self-Regulatory Organizations; Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s (b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on August 16, 1978, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

TEXT OF THE PROPOSED RULE CHANGE

(a) Amendments to the Fee Schedule for Major Services:

Y. PARTICIPANT TERMINAL SYSTEM (PTS)

1. [Rental of] *Full PTS* terminal *(one CRT screen and printer)* [$445] *$595* per month plus any applicable taxes and related communications line costs.

2. Advanced PTS terminal (one CRT screen plus a separately addressable higher speed printer), $645 per month plus any applicable taxes and related communications line costs.

3. Advanced 2 CRT PTS terminal (two CRT screens plus a separately addressable higher speed printer), $845 per month plus any applicable taxes and related communications line costs.

4. Dial-in-terminal service charge: a. Participants, $75 per month. b. Non-Participants (ID confirmations only), $120 per year.

[2. Inquires (other than ID inquiries) or automatic notifications through Participant's terminal] [No charge for first 2,000 units per month; 1 cent for each additional unit.]

5. Unsolicited messages, 5 cents per message.

6. Inquires, 5 cents per inquiry.

7. Reports: a. The Dropped Delivery Report; b. The Dropped COD Report; c. The Cash Dividend Report; $25 per month per report series plus 5 cents per line.

8. Pre-Update Edits, 5 cents per edit.

9. Broadcast, 12 cents per 300-character message per addressee.

The fee schedule for major services was originally filed on form 19b-4A, file No. SR-NYSE-75-19. Fees for PTS were originally filed on form 19b-4A, File No. SR-DTC-76-8. A revised fee schedule for major services was filed on form 19b-4A, file No. SR-DTC-78-6.

STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule change is as follows:

The purpose of the proposed rule change is to establish fees for PTS which will reflect the Depository Trust Co.'s (DTC) costs more accurately than do the present fees.

The proposed rule change relates to DTC's carrying out the purposes of section 17A of the Securities Exchange Act of 1934 (the Act) by equitably allocating fees among DTC participants.

The proposed PTS fees were discussed with a number of participants to determine whether or not they would be likely to give up use of the terminal because of the increased fees. A large majority indicated that they would keep the terminal while a few indicated that they would discontinue PTS use. No written comments on the proposed fees have been solicited or received. All participants have been notified of the proposed fees by a DTC important notice (exhibit 2 to DTC's filing on form No. 19b-4A, file No. SR-DTC-78-12).

DTC perceives no burden on competition by reason of the proposed rule change.

The foregoing rule change has become effective, pursuant to section 19(b)(3) of the Securities Exchange Act of 1934. At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Securities Exchange Act of 1934.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization.

All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 20, 1978.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 21, 1978.

[FR Doc. 78-27434 Filed 9-28-78; 8:45 am]

[8010-01]

[File No. 1-6782]

MEDENCO, INC.

Application To Withdraw From Listing and Registration

SEPTEMBER 22, 1978.

The above-named issuer has filed an application with the Securities and Exchange Commission, pursuant to section 12(d) of the Securities Exchange Act of 1934 and rule 12d2-2(d) promulgated thereunder, to withdraw the specified security from listing and registration on the American Stock Exchange, Inc. ("Amex").

The reasons alleged in the application for withdrawing this security from listing and registration include the following:

The common stock of Medenco, Inc. (the "Company"), has been listed for trading on the Amex since December 17, 1971. On February 22, 1978, the stock was also listed for trading on the New York Stock Exchange, Inc. ("NYSE"), and concurrently therewith, such stock was suspended from trading on the Amex. In making the decision to withdraw its common stock from listing and registration on the Amex, the Company considered the direct and indirect expenses involved in maintaining a dual listing and has determined that a dual listing would be of little benefit to its stockholders.

The application relates solely to the withdrawal from listing and registration on the Amex and shall have no effect on the continued listing of such common stock on the NYSE. The Amex has posed no objection in this matter.

Any interested person may, on or before October 20, 1978, submit by letter to the Secretary of the Securities and Exchange Commission, Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission will, on the basis of the application and any other information submitted to it, issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-27430 Filed 9-28-78; 8:45 am]

[8010-01]

[Release No. 34-15176; File No. SR-MSE-78-18]

MIDWEST STOCK EXCHANGE, INC.

Self-Regulatory Organizations; Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on September 5, 1978, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

Additions Italicized—[Deletions Bracketed]

ARTICLE VIII

Arbitration of Member Disputes

Rule 24. All disputes between members or their nominees, in regard to transactions effected on the Options Floor shall be resolved by the Committee on Floor Procedure—Options Floor, if both parties to such a dispute agree to be bound by the decision of that Committee. All disputes between members or their nominees, in regard to transactions effected on the Equity Floor shall be resolved by the Committee on Floor Procedure—Equity Floor, if both parties to such a dispute agree to be bound by the decision of that Committee.

If the parties to the dispute cannot agree to be bound by either Committee's determination, resolution shall be by an Arbitration Panel whose resolution of the dispute shall be final. The Arbitration Panel shall be composed of an odd number of panelists who shall be selected as follows:

Each of the parties to the dispute shall select one member of the appropriate Committee on Floor Procedure to serve as panelist on the Arbitration Panel. The Panelists so selected shall then among them agree on the selection of one or more additional panelists: Provided, That the additional panelists so selected are either members or representatives of member organizations of the Exchange: And provided further, That no member of the Arbitration Panel may be a person

with a direct or indirect financial interest in the claim. In the event that the initial panelists selected by the parties to the dispute cannot agree on the selection of the above-mentioned additional panelist or panelists, as they case may be, then in that event such additional panelist(s) shall be appointed by the appropriate Committee on Floor Procedure, except that any members of the Committee who either have already been selected to serve on the Arbitration Panel or who have a direct or indirect financial interest in the claim shall not participate in the selection of such additional panelist(s). Parties interested in the proceedings before such Arbitration Panel may make oral and written submissions thereto: Provided, That any such submission must be made within seven calendar days of the selection of the Abritration Panel, or, if the Arbitration Panel determines that delay in the resolution of the dispute may increase the loss, within such shorter period of time as the Arbitration Panel, in its discretion may prescribe.

MSE'S STATEMENT OF BASIS AND PURPOSE

The basis and purpose of the foregoing proposed rule change is as follows:

The purpose of the proposed rule change is to provide an arbitration forum for the resolution of disputes between Midwest Stock Exchange members.

The proposed rule change protects the public investor by providing member firms of the Midwest Stock Exchange an orderly and expeditious method of resolving disputes.

The Midwest Stock Exchange, Inc., has neither solicited nor received any comments.

The Midwest Stock Exchange, Inc., believes that no burdens have been placed on competition.

On or before November 3, 1978, or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the above-mentioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 20, 1978.

For the Commission, By the Division of Market Regulation, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 20, 1978.

[FR Doc. 78-27435 Filed 9-28-78; 8:45 am]

[8010-01]

[Release No. 34-15175; File No. SR-NYSE-78-48]

NEW YORK STOCK EXCHANGE, INC.

Self-Regulatory Organizations; Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on August 21, 1978, the above-mentioned self-regulatory organization filed with the Securities and Exchange Commission a proposed rule change as follows:

EXCHANGE'S STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED AMENDMENT

The proposed amendments: (1) Rescind rules requiring minimum time of maturity for subordinated loan agreements for the purchase of a membership and permit repayment to be based upon the value of a membership at maturity of the loan; (2) adopt specific rule provisions for inclusion in a-b-c agreements; and (3) rescind required standards for determining partners' stockholders' respective financial interests in any membership financed by the member organization.

EXCHANGE'S STATEMENT OF PURPOSE OF PROPOSED AMENDMENTS

The purpose of the proposed amendments is to:

(1) Provide greater flexibility to members in negotiating the terms for financing a membership through a subordinated loan agreement with a nonmember by rescinding required minimum times of maturity and allowing repayment to be based upon the seat value at maturity;

(2) Facilitate the transfer of memberships financed pursuant to an a-b-c agreement by requiring new agreements to specify: (i) That upon the occurrence of an event which triggers the election of a-b-c agreement options, the member has 30 days, or such longer period as specified in the agreement, to elect option (a) (retain the membership), (ii) that if the member does not exercise option (a), the member organization would have an additional 30 days, or such longer period specified in the agreement, to require the member to exercise option (b) (sell membership and pay proceeds to member organization) or option (c) (transfer membership for nominal consideration to person designated by member organization), (iii) that the member would sell the membership and pay the proceeds to the member organization, if, at the end of the time periods, the member organization has not elected option (b) or (c), and (iv) that any dispute concerning the transfer of an a-b-c seat would be settled by arbitration; and

(3) Allow member organizations to determine how the risks in the value of a membership financed by the member organization are to be apportioned among the members and partners or stockholders by rescinding prescribed formulas. (An a-b-c agreement is utilized when it is intended that a portion of the risk in the fluctuation of seat value shall rest with the partners or stockholders of the member organization financing the membership.)

The Exchange feels that the proposed amendments requiring that any controversy arising from a subordinated loan or a-b-c agreement be arbitrated in accordance with article VIII of the constitution are necessary to allow for an orderly administration of the Exchange and its seat market. As Exchange membership is limited to 1,366 regular members, each membership must be fully utilized. Experience has shown that controversies arising from such agreements, and resulting protacted legal proceedings delay the transfer of memberships. Requiring controversies to be adjudicated through arbitration will reduce such delays because: Generally a shorter time period will be required to bring a matter to a hearing; arbitration proceedings are more flexible than legal proceedings; and arbitration panels are more conversant with such agreements and the workings of the seat market and industry in general.

EXCHANGE'S STATEMENT OF BASIS UNDER THE ACT

The basis under the Act for the proposed amendments is sections 6(b)(1), 6(b)(2), and 6(b)(5).

The proposed amendments requiring inclusion of specific provisions in subordinated loan and a-b-c agreements and the existing requirements that such agreements be approved by the Exchange are consistent with section 6(b)(1) in that they are intended to

insure that the agreements comply with the standards set forth in the rules of the Exchange.

The proposed amendments providing greater flexibility in the terms of subordinated loan agreements and reducing protracted delays in the transfer of a-b-c memberships by requiring specific provisions therein are consistent with section 6(b)(2) in that they enhance the ability of a natural person who is or is associated with a registered broker or dealer to become a member of the Exchange.

The proposed rescissions of the minimum time of maturity requirements for subordinated loan agreements and the required standards for determining partners' or stockholders' interests in a membership financed by a member organization are consistent with section 6(b)(5) in that they may remove rules pertaining to matters not related to the purposes of the Act or the administration of the Exchange. In addition, the proposed amendments requiring that any controversy arising from a subordinated loan or a-b-c agreement be arbitrated in accordance with the constitution are necessary for an orderly administration of the Exchange and its seat market.

EXCHANGE'S COMMENTS RECEIVED FROM MEMBERS, PARTICIPANTS, OR OTHERS ON PROPOSED AMENDMENTS

No comments were solicited or received.

EXCHANGE'S STATEMENT OF BURDEN ON COMPETITION

No burden on competition will be imposed by the proposed amendments.

On or before November 3, 1978, or within such longer period: (i) As the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which the above mentioned self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Securities and Exchange Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 20, 1978.

For the Commission, by the Division of Market Regulation pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

SEPTEMBER 19, 1978.

[FR Doc. 78-27436 Filed 9-28-78; 8:45 am]

[8010-01]

[Release No. 10415; 812-4348]

TAX-EXEMPT BOND FUND OF VIRGINIA FIRST SERIES (AND SUBSEQUENT SERIES) AND CRAIGIE INC.

Filing of Application for an Order of the Commission Granting Exemptions From Provisions

SEPTEMBER 21, 1978.

Notice is hereby given that The Tax-Exempt Bond Fund of Virginia, First Series (and Subsequent Series) (the "Fund"), a unit investment trust registered under the Investment Company Act of 1940 (the "Act") and its sponsor, Craigie Inc. (the "Sponsor") (hereinafter the Sponsor and the Fund are collectively referred to as "Applicants"), Fidelity Building, Ninth and Main Streets, Richmond, Va. 23219, have filed an application on August 10, 1978, and an amendment thereto on September 19, 1978, pursuant to Section 6(c) of the Act for an order of the Commission exempting the Applicants from the provisions of Section 14(a) of the Act and exempting the frequency of the capital gains distributions of the fund and the secondary market operations of the Sponsor from the provisions of rule 19b-1 and rule 22c-1, respectively, under the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below.

Series 1 of the Fund ("Series 1") is a unit investment trust, and is the first of a series of similar but separate trusts that the Sponsor intends to form (hereinafter Series 1 and all such Subsequent Series are collectively referred to as the "Series"). The Series will be created under the laws of the State of New York or the Commonwealth of Virginia pursuant to separate trust agreements that will contain certain standard terms and conditions of trust common to all the Series. The Applicants represent that the investment objective of each Series will be to seek both the preservation of capital and current distributions of tax-exempt income through the investment in a portfolio of securities consisting of (i) debt obligations of political subdivisions, public authorizations and agencies of the Commonwealth of Virginia (the "Bonds") and (ii) subject to certain limitations, Units of previously issued Series of the Fund (the Bonds and previously issued Units are collectively called herein the "Trust Securities"). The Trust Securities that will constitute the portfolio of each Series will be selected in advance and will be identifiable in respect of each Series on the date of deposit with the Trustee.

The Sponsor has filed a Form S-6 Registration Statement under the Securities Act of 1933 ("1933 Act") covering fractional undivided interests in Series 1 to be offered to investors at a public offering price set forth in the prospectus included in the S-6 Registration Statement. The 1933 Act Registration Statement has not yet become effective. The Sponsor has also filed a Form N-8A Notification of Registration and a Form N-8B-2 Registration Statement under the Act relating to the Fund.

Each Series of the Fund will be governed by the provisions of a trust agreement (the "Agreement") to be entered into by the Sponsor and a corporation organized and doing business under the laws of the United States or New York or Virginia, that is authorized under such laws to exercise corporate trust powers and having at all times an aggregate capital, surplus, and undivided profits of not less than $50,000,000 ("Trustee"). It is contemplated that United States Trust Company of New York will serve as Trustee for Series 1. Standard & Poor's Corporation will serve as Evaluator for Series 1. A separate Agreement will be entered into each time a Series is created and activated and the Trust Securities that comprise its portfolio (or delivery statements relating to contracts for the purchase of such Trust Securities together with funds represented by cash or an irrevocable letter of credit issued by a commercial bank in the amount required for their purchase) are deposited with the Trustee. Each Series will be substantially identical except as to size, number of Units and the individual Trust Securities in the portfolio.

When a Series of the Fund is created, the Sponsor and the Trustee will enter into an Agreement and the Trust Securities to constitute such Series of the Fund (or delivery statements relating thereto and funds for the purchase thereof as set forth above) will be delivered to and deposited with the Trustee by the Sponsor. Substantially concurrently, the Trustee will issuee in the name of the Sponsor, or such other name or names as the Sponsor may direct, one or more

certificates evidencing the ownership of all of the undivided interests in such Series of the Fund. These Units will be separately offered for sale to the public at prices based upon their then respective current net asset values plus a sales charge, after the registration statement filed in respect thereto under the 1933 Act has become effective.

The Applicants state that the Trust Securities will not be pledged or be in any other way subjected to any debt at any time after they are deposited with the Trustee. The Sponsor expects to accumulate Trust Securities for the purpose of deposit in Series 1 and expects to follow a similar procedure of accumulating Trust Securities for each Subsequent Series.

The assets of the Fund may consist of Bonds initially deposited, such Bonds as may continue to be held from time to time in exchange for or substitution of any of the Bonds, accrued and undistributed interest, undistributed cash and Units of previously issued Series of the Fund. Certain of the Bonds may from time to time be sold under the circumstances set forth in the Agreement, or may be redeemed or may mature in accordance with their terms. The proceeds from such dispositions will be distributed to the holders of Units of the Trust ("Unitholders") and not reinvested.

Each Unit of the Fund will represent a fractional undivided interest, the numerator of the fractional interest represented will be 1 and the denominator will be the number of Units issued and outstanding in any particular Series. Units are redeemable, and in the event that any Units are redeemed, the fractional undivided interest represented by each Unit will be increased accordingly. Units will remain outstanding until redeemed or until the termination of the Agreement. The Agreement may be terminated by 66⅔ percent agreement of the Unit-holders of a Series or, in the event that the value of Trust Securities falls below an amount specified, either upon direction of the Sponsor to the Trustee or by the Trustee without such direction. There is no provision in the Agreement for the issuance of any Units after the initial issuance and such activity will not take place (except to the extent that the secondary trading by the Sponsor in the Units is deemed the issuance of Units under the Act).

The Sponsor, while under no obligation to do so, intends to maintain a market for whole Units of the Fund and to offer to purchase such Units at prices in excess of the redemption price as set forth in the Agreement. In the absence of such a market, Unitholders may only be able to dispose of their Units by redemption.

SECTION 14(a)

Section 14(a) of the Act, in substance, provides that no registered investment company and no principal underwriter for such a company shall make a public offering of securities of which such company is the issuer unless (1) the company has a net worth of at least $100,000; (2) at the time of a previous public offering it had a net worth of $100,000; or (3) provision is made that a net worth of $100,000 will be obtained from not more than 25 responsible persons within ninety days, or the entire proceeds received, including sales charge, will be refunded.

The Applicants seek an exemption from the provisions of Section 14(a) of the Act in order that a public offering of Units of the Fund as described above may be made. In connection with the requested exemption from Section 14(a) the Sponsor agrees (1) to refund, on demand and without deduction, all sales charges to purchasers of Units of a Series if, within ninety days from the time that a registration statement for a Series becomes effective under the 1933 Act, the networth of the Series shall be reduced to less than $100,000, or if such Series is terminated; (2) to instruct the Trustee on the date Trust Securities are deposited in each Series that in the event that redemption by the Sponsor of Units constituting a part of the unsold Units shall result in that Series having a net worth of less than 40 percent of the principal amount of Trust Securities originally deposited for such Series, the Trustee shall terminate the Series in the manner provided in the Agreement and distribute any Trust Securities or other assets deposited with the Trustee pursuant to the Agreement as provided therein; and (3) in the event of termination for the reasons described in (2) above, to refund any sales charges to any purchasers of Units purchased from the Sponsor, on demand and without any deduction. Thus, the Applicants represent that it is highly unlikely that, except during the course of liquidation, the net worth of any Series would ever decline to $100,000 or less.

RULE 19b-1

Rule 19b-1 provides in substance that no registered investment company which is a "regulated investment company" as defined in section 851 of the Internal Revenue Code shall distribute more than one capital gain dividend in any one taxable year of such investment company. Paragraph (b) of the rule contains a similar prohibition for a company not a "regulated investment company" but permits a unit investment trust to distribute capital gain dividends received from a "regulated investment company" within a reasonable time after receipt.

Distributions of interest and principal on each Series will be made to Unit- holders quarterly. The Applicants represent that distributions of principal on each Series constituting capital gains to Unitholders may arise in the following instances: (1) If an issuer calls or redeems an issue of Bonds held in the portfolio, the sums received by the Fund will be distributed on a pro-rata basis to each Unitholder on the next distribution date; (2) if Units are redeemed by the Trustee and Trust Securities from the portfolio are sold to provide the funds necessary for such redemption, each Unitholder will receive his pro-rata portion of the proceeds from the Trust Securities sold over the amount required to satisfy such redemption distribution; (3) if Bonds held in the portfolio are sold to maintain the investment stability of a Series of the Fund, the sums received by the Fund may be distributed on a pro-rata basis to each Unitholder on the next distribution date; and (4) as regular distributions of principal and any pre-payments of principal are declared on an issue of Bonds held in the portfolio, the sums received by the Fund will be distributed on a pro-rata basis to each Unitholder on the next distribution date. In such instances, a Unitholder may receive in his distribution funds that constitute capital gains, because in some cases the value of the Trust Securities redeemed or sold may have increased since the date of their acquisition by the Fund.

As noted above, Paragraph (b) of rule 19b-1 provides that a unit investment trust may distribute capital gain dividends received from a "regulated investment company" within a reasonable time after receipt. The Applicants assert that the purpose behind such provision is to avoid forcing unit investment trusts to accumulate valid distributions received throughout the year and distribute them only at year end, and that the operations of the Applicants in this regard are squarely within the purpose of such provision. However, in order to comply with the literal requirements of the Rule, each Series of the Fund would be force to hold any monies that would constitute capital gains upon distribution until the end of its taxable year. The application contends that such practice would clearly be to the detriment of the Unitholders.

In support of the requested exemption, the Applicants state that the dangers which rule 19b-1 is intended to guard against do not exist in the situation at hand because neither the Sponsor nor the Fund has control over events which might trigger capital gains, e.g., the tendering of Units for

redemption and the prepayment of portfolio Bonds by the issuers. In addition, it is contended that any capital gains distribution will be clearly indicated as capital gains in the accompanying report by the Trustee to the Unit- holder. Furthermore, the Applicants assert that the sale of Bonds in an effort to maintain the investment stability of a Series of the Fund is an activity designed generally to prevent or to retard deterioration of values when certain adverse factors exist. These factors include a default in the payment of principal or interest on Bonds, an action involving the issuer thereof that will adversely affect its ability to continue payment of the principal and the interest on its Bonds, or an adverse change in the market, revenue or credit factors affecting the investment stability of the Bonds. Finally, the Applicants contend that sale of Bonds in an effort to maintain investment stability of any Series is not expected to result in capital gains distributions to the Fund or its Unitholders because the above factors will normally have a depressing effect on the market value of the Bonds.

RULE 22c-1

The Applicants state that following the initial offering period, the Sponsor, while not obligated to do so, intends to offer to purchase whole Units in the secondary market at prices based on the offering side evaluation of the Trust Securities in any Series, determined on the last business day of each week, effective for all sales made during the following week.

The Applicants also state that the Sponsor has undertaken to adopt a procedure whereby the Evaluator, without a formal evaluation, will provide estimated evaluations on trading days. In the case of a repurchase, if the Evaluator cannot state that the previous Friday's price is at least equal to the current bid price, the Sponsor will order a formal evaluation. The Sponsor agrees that, in the case of the resale of Units in the secondary market, if the Evaluator cannot state that the previous Friday's price is not more than one-half point ($5.00 on a unit representing $1,000.00 principal amount of underlying Trust Securities) greater than the current offering price, a formal evaluation will be ordered. Under these circumstances the Applicants contend that the exemption of the Sponsor from the provisions of rule 22c-1 will in no way affect the operations of the Fund and will benefit the Unitholders by providing a repurchase price for their Units that is in excess of the current net asset value of such Units as computed for redemption purposes.

Rule 22c-1 provides, in pertinent part, that no registered investment company issuing any redeemable security, and no dealer in any such security, shall sell, redeem, or repurchase any such security except at a price based on the current net asset value of such security which is next computed after receipt of a tender of such security for redemption or of an order to purchase or sell such security.

The Applicants state that rule 22c-1 has two purposes: (1) to eliminate or to reduce any dillution of the value of outstanding redeemable securities of registered investment companies which might occur through the sale, redemption, or repurchase of such securities at prices other than their current net asset values; and (2) to minimize speculative trading practices in the securities of registered investment companies.

The secondary market activities of the Sponsor and the manner for the acquisition by investors of new Units, may be deemed to violate rule 22c-1 because of the absence of daily pricing. The Applicants contend, however, that the purposes of rule 22c-1 will not be frustrated by the Sponsor in the proposed secondary market activities. The Applicants assert that the pricing of Units by the Sponsor in the secondary market will in no way dilute the assets of the Fund, and that Unitholders will benefit from the Sponsor's pricing procedure in the secondary market because they will normally receive a higher repurchase price for their Units than they could obtain by redeeming their Units at the current net asset value, and that this will be accomplished without the cost burden to the Fund of daily evaluations of the Units' redemption value.

The Applicants also contend that speculation in Units of any Series is unlikely because price changes are limited in respect to the kind of Trust Securities that will be held by such Series. In addition, the Applicants argue that because of the nature of the Trust Securities price changes are gradual and depend largely on general changes in interest rates. To avoid the Sponsor receiving more than the specified sales charge on the resale of Units, the Sponsor has undertaken not to resell in the secondary market any Units that it may repurchase at a price below the offering side evaluation of the Trust Securities in any Series.

The Applicants therefore request an exemption from the provisions of rule 22c-1 for Series 1 and for all subsequently created Series insofar as the rule may apply after completion of the primary distribution of Units of such Series.

Section 6(c) of the act provides, in pertinent part, that the Commission, by order upon application, may conditionally or unconditionally exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of the Act or of any rule or regulation under the Act, if and to the extent such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act.

Notice is further given that any interested person may, not later than October 13, 1978, at 5:30 P.M., submit to the Commission in writing a request for a hearing on the application accompanied by a statement as to the nature of his interest, the reasons for such request, and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission shall order a hearing thereon. Any such communication should be addressed: Secretary, Securities and Exchange Commission, Washington, D.C. 20549. A copy of such request shall be served personally or by mail upon the Applicants at the address stated above. Proof of such service (by affidavit, or in the case of an attorney-at-law by certificate) shall be filed contemporaneously with the request. As provided by rule 0-5 of the rules and regulations promulgated under the Act, an order disposing of the application herein will be issued as of course following said date unless the Commission thereafter orders a hearing upon request or upon the Commission's own motion. Persons, who request a hearing or advice as to whether a hearing is ordered, will receive any notices and orders issued in this matter, including the date of the hearing (if ordered) and any postponements thereof.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

GEORGE A. FITZSIMMONS,
Secretary.

[FR Doc. 78-27431 Filed 9-28-78; 8:45 am]

[8010-01]

[Release No. 34-15190; File No. SR-CSE-78-2]

CINCINNATI STOCK EXCHANGE

Self-Regulatory Organizations; Proposed Rule Change

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), as amended by Pub. L. No. 94-29, 16 (June 4, 1975), notice is hereby given that on September 25, 1978, the above-mentioned self-regulatory organization filed with the Secu-

rities and Exchange Commission a proposed rule change as follows:

STATEMENT OF THE TERMS OF SUBSTANCE OF THE PROPOSED RULE CHANGE

The Exchange proposes to amend its Rule 9D3 (temporary), concerning multiple-dealer trading, to extend the period of effectiveness of the Rule, and the duration of the pilot program authorized thereby, to January 31, 1980, or such earlier date as the Exchange's Board of Trustees may determine. The proposed rule change would be effected by deleting the numerals "1979" and inserting in their place the numerals "1980" in the last sentence of the second paragraph of the Rule.

PURPOSE OF PROPOSED RULE CHANGE

The purpose of the proposed rule change is to extend the duration of the Exchange's pilot program for an additional year, until January 31, 1980. At the present time, with the Rule's expiration date less than 5 months away, it has become increasingly difficult for the Exchange to plan, negotiate, and enter into long-term business commitments. This problem arises in dealings with suppliers, negotiations with potential facilities managers, and attempts to solicit prospective Exchange members. In addition, the Exchange finds it difficult to enter into leases and similar long-term commitments—including proposed enhancements of its electronic communications system—while the term of its continued existence remains uncertain from a legal point of view.

The Exchange's experimental program has existed only some 5 months. This has been an insufficient amount of time for the Exchange, the Commission, or the industry fully or even substantially to assess the viability of the Exchange's pilot program and the benefits and difficulties inherent in this kind of trading facility. The Exchange believes, as stated in the Commission's release approving the pilot program, that its experimental trading system and the technological features employed in this experiment should be of assistance to the Commission in assessing the implications of national markets system initiatives. The benefits of the system, however, cannot be expected to be experienced or fully reviewed within the relatively brief existence of the Exchange. Indeed, data gathering and analysis has only commenced and review and collection of data over a longer period of time is essential for a realistic evaluation of the program. Additional time is also needed to provide an opportunity for additional participants to join the Exchange. Broader participation will enhance the value of the experiment and provide a better data base for analysis.

Perhaps even more significantly, the Commission now has an important opportunity to demonstrate its oft-stated commitment to encouraging private initiatives in development of a national market system. In fact, disapproval of the requested extension could serve to stifle innovative industry action. Approval, on the other hand, would underscore the seriousness of the Commission's intention to rely principaly on the private sector in this critical area.

BASIS UNDER THE ACT FOR PROPOSED RULE CHANGE

The principal purpose of the proposed rule change is to facilitate removal of impediments to and perfection of the mechanism of a free and open market and a national market system. (Securities Exchange Act, section 6(b)(5).)

COMMENTS RECEIVED FROM MEMBERS, PARTICIPANTS OR OTHERS ON PROPOSED RULE CHANGE

No comments on the proposed rule change have been received.

BURDEN ON COMPETITION

The Exchange believes that the proposed rule change imposes no burden on competition. Indeed, it believes that by providing an "experiment" in the application of electronic communication equipment to trading in multiply traded securities, it is fostering fair competition among brokers, among dealers, and among exchange markets, as contemplated by section 11A(a)(1)(C)(ii) of the act.

EXTENSION OF TIME PERIOD FOR COMMISSION ACTION

Within 35 days of the date of publication of notice of the proposed rule change in the FEDERAL REGISTER (November 3, 1978), or within such longer period (i) as the Commission may designate, up to 90 days after such date, if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Persons desiring to make written submissions should file six copies thereof with the Secretary of the Commission, Washington, D.C. 20549. Copies of the filing with respect to the foregoing and of all written submissions will be available for inspection and copying in the Public Reference Room, 1100 L Street NW., Washington, D.C. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number referenced in the caption above and should be submitted on or before October 30, 1978.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: September 25, 1978.

SHIRLEY E. HOLLIS,
Assistant Secretary.

[FR Doc. 78-27659 Filed 9-28-78; 8:45 am]

[1505-01]

DEPARTMENT OF THE TREASURY

Fiscal Service

[Dept. Circ. 570, 1978; Rev., Supp. No. 4]

SURETY COMPANIES ACCEPTABLE ON FEDERAL BONDS

Continental Surety and Fidelity Insurance Co.

Correction

In FR Doc. 78-26716, appearing at page 43403 in the issue of Monday, September 25, 1978, the last word in the sixth line of column one on page 43404 should read, "Littleton" and the word "Colorado" should follow the period in the seventh line.

[4810-22]

Office of the Secretary

PNEUMATIC MARINE FENDERS FROM JAPAN

Antidumping; Determination of Sales at Not Less Than Fair Value

AGENCY: Department of the Treasury.

ACTION: Determination of sales at not less than fair value.

SUMMARY: This notice is to advise the public that an antidumping investigation has resulted in a determination that pneumatic marine fenders from Japan are not being, nor are likely to be, sold at less than fair value within the meaning of the Antidumping Act, 1921. Sales at less than fair value generally occur when the price of the merchandise sold for exportation to the United States is less than the price of such or similar merchandise sold in the home market or to third countries.

EFFECTIVE DATE: September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Stephen Nyschot, Operations Officer, Duty Assessment Division, U.S.

Customs Service, 1301 Constitution Avenue NW., Washington, D.C. 20229, 202-566-5492.

SUPPLEMENTAL INFORMATION: Information was received in proper form on November 27, 1977, from counsel acting on behalf of Seaward International, Inc., Falls Church, Va., and Samson Ocean Systems, Inc., Boston, Mass., alleging that pneumatic marine fenders from Japan were being sold in the United States at less than fair value, thereby causing injury to, or the likelihood of injury to, an industry in the United States, within the meaning of the Antidumping Act, 1921, as amended (19 U.S.C. 160 et seq.) (referred to in this notice as "the Act"). On the basis of this information and subsequent preliminary investigation by the Customs Service, an "Antidumping Proceeding Notice" was published in the FEDERAL REGISTER of December 28, 1977 (42 FR 64753). A "Notice of Tentative Determination of Sales at Not Less Than Fair Value" was published in the FEDERAL REGISTER of July 5, 1978 (43 FR 29046). A statement of reasons was published in the above-mentioned notice and interested persons were afforded an opportunity to make written submissions and present oral views. None of the interested parties made written submissions or requested an opportunity to present oral views.

For purposes of this notice, the term "pneumatic marine fenders" means pneumatic marine fenders used on vessels, docks, and quays to absorb impact, provided for in item 790.39, Tariff Schedules of the United States.

DETERMINATION OF SALES AT NOT LESS THAN FAIR VALUE

On the basis of the information developed in the Customs Service investigation and for the reasons noted below, pursuant to section 201(b) of the Act (19 U.S.C. 160 (b)), I hereby determine that the purchase price of pneumatic marine fenders from Japan is not less, nor is likely to be less, than the fair value of such or similar merchandise.

STATEMENT OF REASONS ON WHICH THIS DETERMINATION IS BASED

The reasons and bases for the above determination are as follows:

a. *Scope of the investigation.* It appears that all imports of the subject merchandise from Japan were manufactured by Yokohama Rubber Co., Ltd., Tokyo, Japan. Therefore, the investigation was limited to this manufacturer.

b. *Basis of comparison.* For the purpose of considering whether the merchandise is being, or is likely to be, sold at less than fair value within the meaning of the Act, the proper basis of comparison is between purchase price and the home market price of such merchandise. Purchase price, as defined in section 203 of the Act (19 U.S.C. 162), was used since the export sales compared were made to unrelated Japanese trading companies for resale to the United States. Home market price, as defined in § 153.2, Customs Regulations (19 CFR 153.2), was used since such merchandise was sold in the home market in sufficient quantities to provide a basis of comparison for fair value purposes.

In accordance with § 153.31(b), Customs Regulations (19 CFR 153.31(b)), pricing information was obtained concerning sales in the home market and to the United States during the period January 1 through December 31, 1977.

c. *Purchase price.* For the purpose of this determination, purchase price has been calculated on the basis of the c.i.f., c. & f., or f.o.b. packed price to unrelated trading companies for export to the United States, with deductions for ocean freight, insurance, and domestic freight, as appropriate.

d. *Home market price.* For the purpose of this determination, the home market price has been calculated on the basis of the delivered, packed price to unrelated customers in the home market. Adjustments have been made for interest costs, freight, and packing cost differentials, as appropriate, in accordance with § 153.10, Customs Regulations (19 CFR 153.10). The adjustment for interest cost relates to extended payment terms granted to customers in the home market.

Claims made by respondent for adjustments for the following were not allowed: Fluctuation in currency exchange rate, difference in level of trade, and advertising expenses allegedly incurred in the home market. The claim for an adjustment for currency exchange rate fluctuation is based upon respondent's argument that, with respect to a certain sale, it had made a binding offer to sell at a designated price several months before the date of purchase. However, § 153.52(a) of the Customs Regulations (19 CFR 153.52(a)) clearly establishes that the exchange rate in effect on the date of purchase, or agreement to purchase, governs, and the mere existence of a firm offer cannot be considered the date of purchase, or agreement to purchase, until that offer is accepted. In addition, respondent argued that the sale in question was made to a different level of trade from that in the home market. It contends that the sales of the particular size fender in the home market were made to ship chandlers, which allegedly sell directly to end users, whereas the price to the United States was based upon a sale made to the trading company in Japan. However, no information was presented to show that ship chandlers do, indeed, sell only to end users or that the functions they perform are different from those performed by the trading company. In view of this lack of substantiation, no adjustment could be made for differences in level of trade, as provided for by § 153.15 of the Customs Regulations (19 CFR 153.15). The claim for advertising expenses allegedly incurred in the home market did not indicate that the expenses were incurred on behalf of Yokohama's customers, as required by § 153.10 of the Customs Regulations (19 CFR 153.10), and furthermore, inadequate documentation was provided.

e. *Result of fair value comparisons.* Using the above criteria, the comparisons made on 100 percent of the sales of the subject merchandise to the United States indicated that purchase price was not less than the home market price of such merchandise for nearly 99 percent of the total value sold to the United States. In one sale, accounting for slightly over 1 percent of the total value sold to the United States and involving one particular small size pneumatic marine fender, not focused upon by petitioner in this case, purchase price was found to be less than the home market price. However, this margin amounted to roughly 0.3 of 1 percent when weighted over 100 percent of all sales, and is considered to be de minimis in the context of this case.

This determination and the statement of reasons therefor are published pursuant to § 153.34(c) of the Customs Regulations (19 CFR 153.34(c)).

ROBERT H. MUNDHEIM,
General Counsel
of the Treasury.

SEPTEMBER 22, 1978.

[FR Doc. 78-27513 Filed 9-28-78; 8:45 am]

[7035-01]

INTERSTATE COMMERCE COMMISSION

[Notice No. 719]

ASSIGNMENT OF HEARINGS

SEPTEMBER 26, 1978.

Cases assigned for hearing, postponement, cancellation, or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the official docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as

promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 113651 (Sub-267F), Indiana Refrigerator Lines, Inc., is assigned for hearing November 7, 1978, at Boston, Mass., and will be held at Room 501, 150 Causeway, Fifth Floor.

MC 130223 (Sub-M2F), Peter Pan World Travel, Inc., is assigned for hearing November 8, 1978, at Boston, Mass., and will be held at Room 501, 150 Causeway, Fifth Floor.

MC 114552 (Sub-155F), Senn Trucking Co., is assigned for hearing October 30, 1978, at Boston, Mass., and will be held at Room 501, 150 Causeway, Fifth Floor.

MC 133689 (Sub-179F), Overland Express, Inc., is assigned for hearing November 6, 1978, at Boston, Mass., and will be held at Room 501, 150 Causeway, Fifth Floor.

MC 138253 (Sub-8), Monfort Transportation Co., is assigned for hearing October 16, 1978, at Denver, Colo., and will be held at Courtroom 154, Federal Building, 1929 Stout Street.

MC 217 (Sub-19), Point Transfer, Inc., and MC 45194 (Sub-17), Lattavo Brothers, Inc., and MC 45194 (Sub-18F), Lattavo Brothers, Inc., is assigned for hearing November 21, 1978, at Columbus, Ohio, and will be held at Room 228, Federal Building, 85 Marconi Boulevard.

MC 73165 (Sub-427), Eagle Motors Lines, Inc., and MC 87103 (Sub-24F), Miller Transfer & Rigging Co., is assigned for hearing November 21, 1978, at Columbus, Ohio, and will be held at Room 235, Federal Building, 85 Marconi Boulevard.

MC 128273 (Sub-280), Midwestern Distribution, Inc., is assigned for hearing November 15, 1978, at Columbus, Ohio, and will be held at Room 228, Federal Building, 85 Marconi Boulevard.

MC 87103 (Sub-23), Miller Transfer & Rigging Co., is assigned for hearing November 17, 1978, at Columbus, Ohio, and will be held at Room 228, Federal Building, 85 Marconi Boulevard.

MC 139254 (Sub-14F), Brooks Transportation, Inc.,is assigned for hearing November 20, 1978, at Columbus, Ohio, and will be held at Room 228, Federal Building, 85 Marconi Boulevard.

MC 142059 (Sub-23F), Cardinal Transport, Inc., is assigned for hearing November 13, 1978, at Columbus, Ohio, and will be held at Room 228, Federal Building, 85 Marconi Boulevard.

MC 99749 (Sub-5F), Bourne's Transf., Inc., is assigned for hearing November 1, 1978, at Boston, Mass., and will be held at Room 501, 150 Causeway, Fifth Floor.

MC 82492 (Sub-179F), Michigan & Nebraska Transit Co., Inc., is assigned for hearing November 20, 1978, at Columbus, Ohio, and will be held at Room 235, Federal Building, 85 Marconi Boulevard.

MC 115826 (Sub-308F), W. J. Digby, Inc., is assigned for hearing October 18, 1978, at Denver, Colo., and will be held at Courtroom 154, Federal Building, 1929 Stout Street.

MC 138649 (Sub-61F), Donco Carriers, Inc., is assigned for hearing October 17, 1978, at Courtroom 154, Federal Building, 1929 Stout Street, in Denver, Colo.

MC 143993 (Sub-2), Black Hills Trucking, Inc., is assigned for hearing October 11, 1978, at Denver, Colo., and will be held at Courtroom 154, Federal Building, 1929 Stout Street.

MC 1515 (Sub-7) (M1), Greyhound Lines, Inc., is assigned for hearing October 16, 1978, at Gallup, N. Mex., and will be held at The Inn, 3009 West 66, and will be continued October 18, 1978, at Albuquerque, N. Mex., and will be held in Ramada Inn—Downtown, 717 Central NW., and will be continued to October 20, 1978, at Amarillo, Tex., and will be held at the Quality Inn, 2915 I-40 East.

MC 108380 (Sub-94), Johnston's Feul Liners, Inc., is assigned for hearing October 12, 1978, at Denver, Colo., and will be held at Courtroom 154, Federal Building, 1929 Stout Street.

MC 144035 (Sub-2F), Minute Air, Inc., is assigned for hearing October 18, 1978, at Albany, N.Y., and will be held at Room 317, Leo W. O'Brien Federal Building, Clinton and North Pearl Streets.

MC 89578 (Sub-4F), Arthur Brundage, Inc., d.b.a. Oneonta Bus Lines, is assigned for hearing October 16, 1978, at Albany, N.Y., and will be held at Room 317, Leo W. O'Brien Federal Building, Clinton and North Pearl Streets.

MC 104149 (Sub-200F), Osborne Truck Line, Inc., transferred to modified procedure.

MC 118130 (Sub-85), South Eastern XPress, Inc., transferred to modified procedure.

H. G. Homme, Jr.,
Acting Secretary.

[FR Doc. 78-27507 Filed 9-28-78; 8:45 am]

[7035-01]

[Docket No. AB-1 (Sub-No. 57)]

CHICAGO AND NORTH WESTERN TRANSPORTATION CO. ABANDONMENT BETWEEN LAKE CRYSTAL AND WINNEBAGO IN BLUE EARTH AND FARIBAULT COUNTIES, MINN.

Findings

Notice is hereby given pursuant to section 1a(6)(a) of the Interstate Commerce Act (49 U.S.C 1a(6)(a)) that by a decision entered on August 29, 1978, a finding, which is administratively final, was made by the administrative Law Judge, stating that, subject to the conditions for the protection of railway employees prescribed by the Commission in *Oregon Short Line R. Co.-Abandonment Goshen*, 354 ICC 584 (1978), and subject to the further condition that the Chicago, Milwaukee, St. Paul and Pacific Railroad Co. will acquire approximately 1.14 miles of trackage in Faribault County in order to directly serve Winnebago Farmers Elevator Co. and Farmers Union Central Exchange, located at or near Winnebago, Minn., the present and future public convenience and necessity permit the abandonment by the Chicago and North Western Transportation Co. of a portion of its line extending from milepost 0.0 near Lake Crystal, Blue Earth County, Minn., to milepost 24.6 near Winnebago, Faribault County, Minn.; *Provided, however,* That subject to the acquisition of the above trackage rights by the Chicago, Milwaukee, St. Paul and Pacific Railroad Co., the State of Minnesota, its agents or assigns, be granted, for a period not to exceed 180 days, a first and prior right of refusal to purchase applicant's line of trackage extending from milepost 0.0 near Lake Crystal, Blue Earth County, Minn., to milepost 24.6 near Winnebago, Faribault County, Minn., upon like terms and conditions as to any bona fide offer of purchase, or in the absence thereof, at such price and terms as shall be mutually agreed upon. A certificate of abandonment will be issued to the Chicago and North Western Transportation Company based on the above-described finding of abandonment on or before October 30, 1978, unless by October 30, 1978, the Commission further finds that:

(1) A financially responsible person (including a government entity) has offered financial assistance (in the form of a rail service continuation payment) to enable the rail service involved to be continued; and

(2) It is likely that such proffered assistance would:

(a) Cover the difference between the revenues which are attributable to such line of railroad and the avoidable cost of providing rail freight service on such line, together with a reasonable return on the value of such line, or

(b) Cover the acquisition cost of all or any portion of such line of railroad.

If the Commission so finds, the issuance of a certificate of abandonment will be postponed for such reasonable time, not to exceed 6 months, as is necessary to enable such person or entity to enter into a binding agreement, with the carrier seeking such abandonment, to provide such assistance or to purchase such line and to provide for the continued operation of rail services over such line. Upon notification to the Commission of the execution of such an assistance or acquisition and operating agreement, the Commission shall postpone the issuance of such a certificate for such period of time as such an agreement (including any extensions or modifications) is in effect. Information and procedures regarding the financial assistance for continued rail service or the acquisition of the involved rail line are contained in the Notice of the Commission entitled "Procedures for Pending Rail Abandonment Cases" published in the Federal Register on March 31, 1976, at 41 FR 13691, as amended by publication of May 10, 1978, at 43 FR 20072. All interested persons are advised to follow the instructions contained therein as well

as the instructions contained in the above-referenced decision.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-27504 Filed 9-28-78; 8:45]

[7035-01]

[Docket No. AB-102 (Sub-No. 6)]

MISSSOURI-KANSAS-TEXAS RAILROAD CO. ABANDONMENT AND OPERATIONS OVER ITS "PARSONS-COFFEYVILLE BRANCH" NEAR PARSONS AND COFFEYVILLE, KANS.

Findings

Notice is hereby given pursuant to section 1a(6)(a) of the Interstate Commerce Act (49 U.S.C 1a(6)(a)) that by a decision entered on August 4, 1978, a finding, which is administratively final, was made by the administrative law judge, stating that, subject to the conditions for the protection of railway employees prescribed by the Commission in *Oregon Short Line R. Co.-Abandonment-Goshen*, 354 ICC 584 (1978), the present and future public convenience and necessity permit the abandonment of the Missouri-Kansas-Texas Railroad Co. of its branch line extending from milepost A-139.08 at Parsons, Kans. to milepost A-166 at Coffeyville, Kans., a distance of 27 miles, and further providing, that Missouri-Kansas-Texas Railroad Co. maintains in a proper state of repair all grade crossings on the abandonment trackage, and to maintain bridges and culverts on the line reasonably free of debris during the intervening period between the effective date of approval of abandonment and the subsequent removal of track and structure along the railroad right of way. A certificate of abandonment will be issued to the Missouri-Kansas-Texas Railroad Co. based on the above-described finding of abandonment on or before October 30, 1978, unless by October 30, 1978, the Commission further finds that:

(1) A financially responsible person (including a government entity) has offered financial assistance (in the form of a rail service continuation payment) to enable the rail service involved to be continued; and

(2) It is likely that such proffered assistance would:

(a) Cover the difference between the revenues which are attributable to such line of railroad and the avoidable cost of providing rail freight service on such line, together with a reasonable return on the value of such line, or

(b) Cover the acquisition cost of all or any portion of such line of railroad.

If the Commission so finds, the issuance of a certificate of abandonment will be postponed for such reasonable time, not to exceed 6 months, as is necessary to enable such person or entity to enter into a binding agreement, with the carrier seeking such abandonment, to provide such assistance or to purchase such line and to provide for the continued operation of rail services over such line. Upon notification to the Commission of the execution of such an assistance or acquisition and operation agreement, the Commission shall postpone the issuance of such a certificate for such period of time as such an agreement (including any extensions or modifications) is in effect. Information and procedures regarding the financial assistance for continued rail service or the acquisition of the involved rail line are contained in the Notice of the Commission entitled "Procedures for Pending Rail Abandonment Cases" published in the FEDERAL REGISTER on March 31, 1976, at 41 FR 13691, as amended by publication of May 10, 1978, at 43 FR 20072. All interested persons are advised to follow the instructions contained therein as well as the instructions contained in the above-referenced decision.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-27505 Filed 9-28-78; 8:45]

[7035-01]

[Docket No. AB-133]

WARREN & OUACHITA VALLEY RAILWAY CO. ABANDONMENT BETWEEN WARREN AND BANKS IN BRADLEY COUNTY, ARIZ.

Notice of Findings

Notice is hereby given pursuant to section 1a(6)(a) of the Interstate Commerce Act (49 U.S.C. 1a(6)(a)) that by a decision entered on August 10, 1977, a finding, which is administratively final, was made by the Commission, review board No. 5, stating that, the present and future public convenience and necessity permit the abandonment by the Warren & Ouachita Valley Railway Co. of its entire line of railroad, a total of 15.66 miles between Warren and Banks in Bradley County, Ariz.: *Provided*, That Warren & Ouachita Valley Railway Co. shall not sell, lease, exchange, or otherwise dispose of the right-of-way, all bridges, and all culverts on the line (except the easternmost 2 miles) for a period of 120 days following issuance of a certificate unless any responsible State agency or local government or other interested responsible organizations be given the opportunity, to negotiate the purchase of all or any portion of the rail properties of the line to be abandoned for public use at a purchase price on such terms as the parties may agree are just and reasonable. A certificate of abandonment will be issued to the Warren & Ouachita Valley Railway Co. based on the above-described finding of abandonment on or before October 30, 1978, unless by October 30, 1978, the Commission further finds that:

(1) A financially responsible person (including a government entity) has offered financial assistance (in the form of a rail service continuation payment) to enable the rail service involved to be continued; and

(2) It is likely that such proffered assistance would:

(a) Cover the difference between the revenues which are attributable to such line of railroad and the avoidable cost of providing rail freight service on such line, together with a reasonable return on the value of such line, or

(b) Cover the acquisition cost of all or any portion of such line of railroad.

If the Commission so finds, the issuance of a certificate of abandonment will be postponed for such reasonable time, not to exceed 6 months, as is necessary to enable such person or entity to enter into a binding agreement, with the carrier seeking such abandonment, to provide such assistance or to purchase such line and to provide for the continued operation of rail services over such line. Upon notification to the Commission of the execution of such an assistance or acquisition and operating agreement, the Commission shall postpone the issuance of such a certificate for such period of time as such an agreement (including any extensions or modifications) is in effect. Information and procedures regarding the financial assistance for continued rail service or the acquisition of the involved rail line are contained in the notice of the Commission entitled "Procedures for Pending Rail Abandonment Cases" published in the FEDERAL REGISTER on March 31, 1976, at 41 FR 13691, as amended by publication of May 10, 1978, at 43 FR 20072. All interested persons are advised to follow the instructions contained therein as well as the instructions contained in the above-referenced decision.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-27506 Filed 9-28-78; 8:45 am]

[7035-01]

[Notice No. 175]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

OCTOBER 3, 1978

The following are notices of filing of applications for temporary authority under section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an application may be filed with the field official named in the FEDERAL REGISTER publication no later than the 15th calendar day after the date the notice of the

filing of the application is published in the FEDERAL REGISTER. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completeness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC field office to which protests are to be transmitted.

MOTOR CARRIERS OF PROPERTY

MC 30844 (Sub-618TA), filed July 24, 1978. Applicant: KROBLIN REFRIGERATED XPRESS, INC., 2125 Commercial Street, P.O. Box 5000, Waterloo, IA 50704. Representative: John P. Rhodes (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: *Fiberglass silo tops*, from West Union, IA, to Tulsa, OK, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Shafar Fiberglass, P.O. Box 146, West Union, IA 52175. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

NOTE.—Common control may be involved.

MC 43246 (Sub-26TA), filed July 24, 1978. Applicant: BUSKE LINES, INC., an Illinois corporation, 123 West Tyler Street, P.O. Box 349, Litchfield, IL 62056. Representative: Howard Buske (same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Glass containers and alcoholic beverages, glass containers*, from Hillsboro, IL, to Bardstown, KY, Clifton and Lawrenceville, NJ, and *alcoholic beverages*, from Clifton and Lawrenceville, NJ, to Detroit, MI and Chicago, IL, under a continuing contract or contracts with Hiram Walker Importers, Inc., and Hillsboro Glass Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): R. J. Lavigne, Traffic Manager, Hiram Walker Importers, Inc., P.O. Box 14100, Detroit, MI 48214. Martin Mauer, President, Hillsboro Glass Co., Hillsboro, IL 62049. Send protests to: Charles D. Little, District Supervisor, Interstate Commerce Commission, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62701.

MC 44801 (Sub-10TA), filed July 24, 1978. Applicant: DICK HARRIS & SON TRUCKING CO., INC., 4000 Harris Lane, Lynchburg, VA 24501. Representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, NY 10048. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Corrugated containers and sheets*, from the facilities of Chesapeake Container, Inc., in Richmond, VA, to points in NC, DC, and MD. *Materials, supplies, and equipment* used in the manufacture, distribution, and sale of corrugated containers and sheets, from points in NC, DC, and MD, to the facilities of Chesapeake Container, Inc., in Richmond, VA, for 180 days. Supporting shipper(s): Chesapeake Container, Inc., P.O. Box 7694, Richmond, VA 23231. Send protests to: Interstate Commerce Commission, Bureau of Operations, P.O. Box 210, Roanoke, VA 24011.

MC 107496 (Sub-1154TA), filed July 24, 1978. Applicant: RUAN TRANSPORT CORP., an Iowa corporation, 666 Grand Avenue, 3200 Ruan Center, Des Moines, IA 50309. Representative: E. Check (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lactic acid*, in bulk, in tank vehicles, from Texas City, TX, to Grandview, MO, for 180 days. Supporting shipper(s): Patco Products, 13830 Botts Road, Grandview, MO 64030. Send protests to: Herbert W. Allen, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 518 Federal Building, Des Moines, IA 50309.

MC 109692 (Sub-66TA), filed July 24, 1978. Applicant: GRAIN BELT TRANSPORTATION CO., Route 13, Kansas City, MO 64161. Representative: Warren H. Sapp, P.O. Box 16047, Kansas City, MO 64112. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, lumber products, lumber mill products, and veneered lumber mill products*, from the facilities of Weyerhaeuser Co., at or near West Memphis, AR, to points in CO, IL, IN, IA, KS, MI, MN, MO, NE, MN, OK, SD, TX, and WI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Weyerhaeuser Co., 100 South Wacker Drive, Chicago, IL 60606. Send protests to: Vernon V. Coble, District Supervisor, Interstate Commerce Commission, 600 Federal Building, 911 Walnut Street, Kansas City, MO 64106.

MC 113429 (Sub-4TA), filed July 24,1978. Applicant: MICHAEL CONTRIS, d.b.a. CONTRIS TRUCKING, Rural Route No. 1, Harrod, OH 45850. Representative: Michael Contris (same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Rough and machined steel ring gear castings*, between Chicago, IL, on the one hand, and on the other hand, Lima and Columbus, OH, under a continuing contract or contracts with Clark Equipment Co., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Clark Equipment Co., 525 North 24th Street, Battle Creek, MI 49016. Send protests to: Keith D. Warner, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 313 Federal Office Building, 234 Summit Street, Toledo, OH 43604.

MC 113784 (Sub-67TA), filed July 24, 1978. Applicant: LAIDLAW TRANSPORT LTD., 65 Guise Street, Hamilton, Ontario, L8L 4M1. Representative: Douglas R. Gowland (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Foundry sand additives*, from Albion, MI to the international boundary between the United States and Canada located on the Detroit and St. Clair Rivers, for 180 days. Restricted to foreign commerce. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): American Colloid Co., P.O. Box 228, Skokie, IL 60077. Send protests to: Interstate Commerce Commission, Bureau of Operations, 910 Federal Building, 111 West Huron Street, Buffalo, NY 14202.

MC 113784 (Sub-68TA), filed July 24, 1978. Applicant: LAIDLAW TRANSPORT LTD., 65 Guise Street, Hamilton, Ontario L8L 4M1. Representative: Douglas R. Gowland (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cement, in bulk, in tank vehicles*, from the international boundary located on Detroit and St. Clair Rivers to points in MI, for 180 days. Supporting shipper(s): Harbor Sales Co., Inc., 26711 Woodward, Suite 205, P.O. Box 37, Royal Oak, MI 48068. Send protests to: Interstate Commerce Commission, Bureau of Operations, 910

Federal Building, 111 West Huron Street, Buffalo, NY 14202.

MC 114552 (Sub-171TA), filed July 24, 1978. Applicant: SENN TRUCKING CO. (a South Carolina corporation), P.O. Drawer 220, Newberry, SC 29108. Representative: William P. Jackson, Jr., P.O. Box 1240, Arlington, VA 22210. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pipe and fittings* from the facilities of Charlotte Pipe & Foundry Co., at Charlotte and Bakers, NC, to points in the United States in and east of ND, SD, NB, KS, OK, and TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Charlotte Pipe & Foundry Co., P.O. Box 4430, Charlotte, NC 28204. Send protests to: E. E. Strotheid, District Supervisor, Interstate Commerce Commission, Room 302, 1400 Building, 1400 Pickens Street, Columbia, SC 29201.

MC 117119 (Sub-698TA), filed July 24, 1978. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Represenative: L. M. McLean, P.O. Box 188, Elm Springs, AR 72728. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Frozen foods* (except commodities in bulk) from the facilities of Morton Frozen Foods at Crozet, VA to points in CT, DE, MA, NJ, NC, PA, RI, and to New York City, NY, for 180 days. Supporting shipper(s): Morton Frozen Foods, P.O. Box 7547, Charlottesville, VA 22906. Send protests to: District Supervisor William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 117765 (Sub-242TA), filed July 24, 1978. Applicant: HAHN TRUCK LINE, INC. (an Oklahoma corporation), 1100 South MacArthur, P.O. Box 75218, Oklahoma City, OK 73107. Representative: R. E. Hagan (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Newsprint paper and groundwood paper*, from the facilities of Bowater Southern Paper Corp., at or near Calhoun, TN to points in KS, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Bowater Southern Paper Corp., Calhoun, TN 37309. Send protests to: Connie Stanley, Transportation Assistant, Room 240 Old Post Office and Court House Building, 215 Northwest Third, Oklahoma City, OK 73102.

MC 118989 (Sub-200TA), filed July 24, 1978. Applicant: CONTAINER TRANSIT, INC. (a Winconsin corporation), 5223 South 9th Street, Milwaukee, WI 53221. Representative: Rolland K. Draves (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Paper plates, nested*, from Brentwood, NY to the States of IL and WI, for 180 days. Supporting shipper(s): Carnation Paper Products Corp., 86 Emjay Boulevard, Brentwood, NY 11717. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 125918 (Sub-13TA), filed July 24, 1978. Applicant: JOHN A. DIMEGLIO, INC., White Horse Pike, Ancora, NJ 08037. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Precast and prestressed concrete products and materials, equipment and supplies* used in the manufacture, sale and installation of the foregoing commodities (except in bulk) between the facilities of Formigli Corp. at or near Williamstown Junction and Vineland, NJ, on the one hand, and, on the other, points in the states of DE, MD, VA, PA, NY, CN, and DC, for 180 days. Restricted to shipments originating at or destined to the above points. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Formigli Corp., New Freedom Road, Williamstown Junction, NJ 08094. Send protests to: John P. Lynn, Transportation Specialist, Interstate Commerce Commission, 428 East State Street, Room 204, Trenton, NJ 08608.

MC 125918 (Sub-14TA), filed July 24, 1978. Applicant: JOHN A. DIMEGLIO, INC., White Horse Pike, Ancora, NJ 08037. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pipe*, between the facilities of Kerr Concrete Pipe Co., Folsom, NJ, on the one hand, and, on the other, points in DE, MD, VA, PA, NY, CT, and DC, for 180 days. Restricted to shipments originating at and destined to the above named points. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Kerr Concrete Pipe Co., Route 54, Folsom, NJ 08037. Send protests to: John P. Lynn, Transportation Specialists, Interstate Commerce Commission, 428 East State Street, Room 204, Trenton, NJ 08608.

MC 127303 (Sub-45TA), filed July 24, 1978. Applicant: ZELLMER TRUCK LINES, INC., (a Delaware corporation), P.O. Box 343, Granville, IL 61326. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Glass containers and materials* used in the transportation of glass containers (except in bulk) from the facilities of the Thatcher Glass Manufacturing Co., Division of Dart Industries, Inc., at Streator, IL to points in MI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Thatcher Glass Manufacturing Co., General Traffic Manager Donald W. Pixley, 1901 Grand Central Avenue, Elmira, NY 14902. Send protests to: Lois M. Stahl, Transportation Assistant, Interstate Commerce Commission, 219 South Dearborn Street, Room 1386, Chicago, IL 60604.

MC 129788 (Sub-10TA), filed July 24, 1978. Applicant: NASS TRUCK LINES, INC., P.O. Box H, Wenona, IL 61377. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Glass containers and materials* used in the transportation of glass containers (except in bulk) from the facilities of the Thatcher Glass Manufacturing Co., Division of Dart Industries, Inc., at Streator, IL to points in MI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Thatcher Glass Manufacturing Co., Division of Dart Industries, Donald W. Pixley, General Traffic Manager, 1901 Grand Central Avenue, Elmira, NY 14902. Send protests to: Lois M. Stahl, Transportation Assistant, Interstate Commerce Commission, 219 South Dearborn Street, Room 1386, Chicago, IL 60604.

MC 129903 (Sub-10TA), filed July 24, 1978. Applicant: EMPORIA MOTOR FREIGHT, INC., (a Kansas corporation), P.O. Box 1103—Route 5, Emporia, KS 66801. Representative: John L. Richeson, Second and Main—P.O. Box 7, Ottawa, KS 66067. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Soft beverages*, in cans or bottles, from Oklahoma City, OK to Emporia, KS, for 180 days. Applicant states it does not intend to tack or interline. Supporting shipper(s): DeBauge Bros., Inc., d.b.a. Coca-Cola Bottling of Emporia, 2931 West 15th, Emporia, KS 66801. Send protests to: Thomas P. O'Hara, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 256 Federal

Building and U.S. Courthouse, 444 Southeast Quincy, Topeka, KS 66683.

MC 129903 (Sub-11TA), filed July 24, 1978. Applicant: EMPORIA MOTOR FREIGHT, INC., (a Kansas corporation), P.O. Box 1103—Route 5, Emporia, KS 66801. Representative: John L. Richeson, Second and Main—P.O. Box 7, Ottawa, KS 66067. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cereal malt beverages in cans or bottles*, from the facilities of Miller Brewing Co., Fort Worth, TX to Emporia, KS, for 180 days. Applicant states it does not intend to tack or interline. Supporting shipper(s): DeBauge Bros., Inc., 2915 West 15th, Emporia, KS 66801. Send protests to: Thomas P. O'Hara, District Supervisor, Bureau of Operations, Interstate Commerce Commission, 256 Federal Building and U.S. Courthouse, 444 Southeast Quincy, Topeka, KS 66683.

MC 136511 (Sub-24TA), filed July 24, 1978. Applicant: VIRGINIA APPALACHIAN LUMBER CORP., 9640 Timberlake Road, Lynchburg, VA 24502. Representative: E. Stephen Heisley, Attorney, 666 Eleventh Street NW. No. 805, Washington, DC 20001. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *New furniture*, (1) from Richmond and Kenbridge, VA, to points in CO, CA, AZ, UT, OR, WA, WY and ID; and (2) from Galax, VA, and Elkin, NC, to points in AZ, NM, CA, CO, NV, OR, UT and WA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Lea Industries, Inc., Richmond, VA., Vaughan-Bassett Furniture Co., Galax, VA. Send protests to: Interstate Commerce Commission, Bureau of Operations, P.O. Box 210, Roanoke, VA 24011.

MC 140278 (Sub-2TA), filed July 24, 1978. Applicant: BEITZ WRECKER SERVICE, INC., Highway 65, Redfield, AR 72132. Representative: Thomas J. Presson, Lot 27—River Bend Estates, Redfield, AR 72132. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Wrecked or disabled motor vehicles and trailers by wrecker equipment only*, from points in AK, AZ, CA, CT, DE, ID, ME, MD, MA, MI, MN, MT, NE, NV, NH, NJ, NM, NY, ND, OR, PA, RI, SD, UT, VT, WA, WI, and WY, to points in AR, *and replacement vehicles for wrecked or disabled motor vehicles, by use of wrecker equipment only*, from points in AR to points in the origin States named above, for 180 days. Supporting shipper(s): There are approximately (6) statements or support attached to the application which may be examined at the Interstate Commerce Commission in Washington, DC, or copies thereof which may be examined at the field office named below. Send protests to: District Supervisor William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock AR 72201.

MC 143267 (Sub-28TA), filed July 24, 1978. Applicant: CARLTON ENTERPRISES, INC., 4588 State Route 82, Mantua, OH 44255. Representative: Peter A. Greene, 900 17th Street NW., Washington, DC 20006. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Iron and steel articles* from the facilities of Jones & Laughlin Steel Corp. at Pittsburgh and Aliquippa, PA, to points in AR, KS and MO for 180 days. Supporting shipper(s): Jones & Laughlin Steel Corp., 1600 West Carson Street, Pittsburgh, PA 15263. Send protests to: Martin P. Monaghan, Officer in Charge, Interstate Commerce Commission, 731 Federal Building, Cleveland, OH 44199.

MC 143693 (Sub-2TA), filed June 23, 1978. Applicant: DFC TRUCKING CO., 17872 Cartwright Road, Irvine, CA 92705. Representative: Floyd L. Farano, 2555 East Chapman Avenue, Suite 705, Fullerton, CA 92631; and Alan F. Wohlstetter, 1700 K Street NW., Washington, D.C. 20006. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Frozen meat*, for the account of Delly Food Co., and Proficient Food Co., Inc., from Mansfield, TX, to warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. Between the warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. *Canned and packaged foodstuffs* for the account of Delly Food Co., and Proficient Food Co, Inc., from Gardena, Fresno, Los Angeles, Modesto, Paramount, Salinas, San Francisco, San Jose, Santa Fe Springs, Stockton and Tracy, CA, New Orleans, LA, and Dallas and Fort Worth, TX, Cincinnati OH, Holland, MI, Sebastopol, CA, Humboldt, TN, Chicago, IL, and to warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. Between the warehouses and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. *Frozen and fresh fish, poultry, pork; frozen and chilled foodstuffs, including but not limited to chilled ham, bacon, cheese, dairy and non-dairy topping; frozen fruit juice*, for the account of Delly Food Co., and Proficient Food Co., Inc., from Mansfield TX, San Jose, CA, Orlando and Dover, FL, Pennsauken, NJ, Los Angeles, CA, Grand Island, NE, Chicago, IL, Thornton, IL, Little Rock, AR, Delran, NJ, Deerfield, IL, Auburndale, FL, and St. Petersburg, FL, to warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. Between the warehouses and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. *Restaurant supplies restricted to table items only, i.e., paper products, napkins, china, flatware, glassware, silverware, and cloth products*, for the account of Delly Food Co., and Proficient Food Co., Inc., from New Castle, PA, and Toledo, OH, Shreveport, LA, Muskogee, OK, to warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. Between the warehouses and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. *Restaurant maintenance and janitorial supplies, and restaurant kitchen supplies such as paper products, pots, pans, utensils, silverware, dishes and other equipment used in kitchens for the preparation and service of food*, for the account of Delly Food Co., and Proficient Food Co., Inc., from points and places in Los Angeles and Orange Counties, CA, and Chicago, IL, to warehouse and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward, CA, Arlington, TX, Franklin Park, IL, Orlando, FL, and Bridgeport (Logan Township, Gloucester County), NJ. Between the warehouses and distribution centers of Delly Food Co., and Proficient Food Co., Inc., at Irvine and Hayward CA, Arlington, TX, Franklin Park, IL, Orlando FL, and Bridgeport (Logan Township, Gloucester County), NJ, under a continuing contract or contracts with Delly Food Co., and Proficient Food Co., Inc., for 180 days. No control or dual carrier consider-

ations involved. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Delly Food Co., 17872 Cartwright Road, Irvine CA 92705. Proficient Food Co., Inc., 3434 Runze Avenue, Franklin Park, IL 60131. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 144779 (Sub-1TA), filed July 24, 1978. Applicant: AHA, INC. (a Utah corporation), 607 North Main, Panguitch, UT 84759. Representative: Nida Mae Jensen (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Pre-cut cabinets*, from Center, TX, to Cedar City, UT; (2) *lumber*, from Panguitch, UT, to points in TX; and (3) *flat steel*, from Gardena, Los Angeles, and Pittsburgh, CA, to Cedar City, UT, for 180 days. Supporting shipper(s): Cedar City Products Co., 374 North 2690 West, Cedar City, UT 84720 (Louis J. Szepi, Vice President and General Manager). Escalante Sawmills, Inc., P.O. Box 299, Escalante, UT 84726 (Leland R. Hutton, Manager). Morton Metalcraft Co., P.O. Box H, Cedar City, UT 84720 (Robert G. Heather, Purchasing Agent). Send protests to: District Supervisor Lyle D. Helfer, Interstate commerce Commission, 5301 Federal Building, Salt Lake City, UT 84138.

MC 145103 (Sub-2TA), filed July 24, 1978. Applicant: CALHOUN TRANSPORTATION INC., 319 Jacet Road, Kearny, NJ 07032. Representative: Morton E. Kiel, Suite 6193—5 World Trade Center, New York, NY 10048. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are manufactured, dealt in, or used by persons engaged in the plumbing, building, and industrial supply business between facilities of ITT Grinnell Corp. and ITT Grinnell Valve Co., Inc., located at Elmira, NY, Columbia, East Hempfield Township and Wrightsville, PA, Warren, OH, Clito, GA, Henderson, TN, Princeton, KY, Temple, TX, and Indianapolis, IN, on the one hand, and, on the other, points in the United States (except AK and HI), under a continuing contract or contracts with ITT Grinnell Corp., and ITT Grinnell Valve Co., Inc., for 180 days. Supporting shipper(s): ITT Grinnell Corp., ITT Grinnell Valve Co., Inc., 260 West Exchange Street, Providence, RI 02903. Send protests to: Robert E. Johnston, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 9 Clinton Street, Room 618, Newark, NJ 07102.

MC 145103 (Sub-3TA), filed July 24, 1978. Applicant: CALHOUN TRANSPORTATION INC., 319 Jacet Road, Kearny, NJ 07032. Representative: Morton E. Kiel, Suite 6193—5 World Trade Center, New York, NY 10048. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Power vents*, from Mineral Wells, TX, *heating and air conditioning units*, from Columbus, OH, Jackson, MI, and Edison, NJ, *copper tubing*, from Reading, PA, *compressors*, from Sidney, OH, *grills and registers*, from Holland, MI, to points in IN, KY, TN, AL, MS, LA, IL, MN, IA, MO, ND, SD, NE, OK, TX, CO, WY, MT, and AZ. *Such commodities as are dealt in by or used by persons engaged in retail and wholesale sales of heating, air conditioning, building materials, and industrial materials, supplies and equipment*, between Evansville, IN and Minneapolis, MN, on the one hand, and, on the other, points in IN, KY, TN, AL, MS, LA, IL, MN, IA, MO, ND, SD, NE, OK, TX, CO, WY, MT and AZ, under a continuing contract or contracts with National Temperature Control Centers, Inc., subsidiary of ITT Grinnell Corp., for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): National Temperature Control Centers Inc., subsidiary of ITT Grinnell Corp., 260 West Exchange Street, Providence, RI 02903. Send protests to: Robert E. Johnston, District Supervisor, Interstate Commerce Commission, Bureau of Operations, 9 Clinton Street, Room 618, Newark, NJ 07102.

By the Commission.

H. G. Homme, Jr.,
Acting Secretary.

[FR Doc. 78-27334 Filed 9-28-78; 8:45 am]

[7035-01]

[Notice No. 174]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICTIONS

September 28, 1978.

The following are notices of filing of applications for temporary authority under section 210a(a) of the Interstate Commerce Act provided for under the provisions of 49 CFR 1131.3. These rules provide that an original and six (6) copies of protests to an appliction may be filed with the field official named in the Federal Register publication no later than the 15th calendar day after the date the notice of the filing of the application is published in the Federal Register. One copy of the protest must be served on the applicant, or its authorized representative, if any, and the protestant must certify that such service has been made. The protest must identify the operating authority upon which it is predicated, specifying the "MC" docket and "Sub" number and quoting the particular portion of authority upon which it relies. Also, the protestant shall specify the service it can and will provide and the amount and type of equipment it will make available for use in connection with the service contemplated by the TA application. The weight accorded a protest shall be governed by the completness and pertinence of the protestant's information.

Except as otherwise specifically noted, each applicant states that there will be no significant effect on the quality of the human environment resulting from approval of its application.

A copy of the application is on file, and can be examined at the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., and also in the ICC field office to which protests are to be transmitted.

Motor Carriers of Property

MC 52704 (Sub-178TA), filed July 22, 1978. Applicant: GLENN MCCLENDON TRUCKING COMPANY, INC. (an Alabama corporation), P.O. Drawer H, Opelika Highway, Lafayette, AL 36862. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Paper and paper products*, from West Monroe, LA to points in AL, FL, GA, MS, and TN; and (2) *materials, supplies and equipment* used in the manufacture and conversion of paper and paper products (except commodities in bulk), from points in the states named in (1) above to West Monroe, LA, for 180 days. Supporting shipper(s): Olinkraft, Inc., P.O. Box 488, West Monroe, LA 71291. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 106398 (Sub-815TA), filed July 20, 1978. Applicant: NATIONAL TRAILER CONVOY, INC., P.O. Box 3329, 525 South Main, Tulsa, OK 74103. Representative: Irvin Tull, Traffic Manager (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pickup trucks*, in secondary movements, from the facilities of Gladiator, Inc. at Elkhart, IN to points in the United States, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Gladiator, Inc., P.O. Box 2237, Elkhart, IN 46515.

Send protests to: Connie Stanley, Transportation Assistant, Room 240, Old Post Office and Courthouse Building, 215 3rd Street NW., Oklahoma City, OK 73102.

MC 106398 (Sub-816TA), filed July 20, 1978. Applicant: NATIONAL TRAILER CONVOY, INC., 525 South Main, P.O. Box 3329, Tulsa, OK 74103. Representative: Irvin Tull, Traffic Manager (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Pipe, fittings, valves and hydrants*, from the facilities of Clow Corp. at Buckhannon, WV to points in IL, IN, MI, OH, PA, MD, MA, and VA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Clow Corp., 1121 West 22nd, Oakbrook, IL 60521. Send protests to: Connie Stanley, Transportation Assistant, Room 240, Old Post Office and Courthouse Building, 215 3rd Street NW., Oklahoma, OK 73102.

MC 106398 (Sub-817TA), filed July 20, 1978. Applicant: NATIONAL TRAILER CONVOY, INC., P.O. Box 3329, 525 South Main, Tulsa, OK 74103. Representative: Irvin Tull, Traffic Manager (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Transmission poles, structures and accessories*, from the facilities of C-E American Pole Structures at Houston, TX to all points in AL, CO, IA, KY, LA, PA, SC, and VA, for 180 days. Supporting shipper(s): C-E American Pole Structures, P.O. Box 40020, Houston, TX 77040. Send protests to: Connie Stanley, Transportation Assistant, Room 240, Old Post Office and Courthouse Building, 215 3rd Street NW., Oklahoma City, OK 73102.

MC 115162 (Sub-423TA), filed July 22, 1978. Applicant: POOLE TRUCK LINE, INC. (an Alabama corporation), P.O. Drawer 500, Evergreen, AL 36401. Representative: Robert E. Tate, Registered Practitioner (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Petroleum and petroleum products*, in containers, from Port Arthur, TX, to Charleston, SC, for 180 days. Supporting shipper(s): Gulf Oil Company-U.S., 1357 Peachtree Street NE, Atlanta, GA 30309. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 124078 (Sub-840TA), filed July 20, 1978. Applicant: SCHWERMAN TRUCKING CO. (a Wisconsin corporation), 611 South 28th Street, P.O. Box 1601, Milwaukee, WI 53215. Representative: Richard H. Prevette (same address as above). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Cement dust*, in bulk, in tank vehicles, from Bath, PA, to Farmingdale, NY; Lakewood, Watchung, Garwood, Saxton Fassl, Trenton, and Pleasantville, NJ, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Cemdust, Ltd., Box 491, Blairstown, NJ 07823. Send protests to: Gail Daugherty, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, U.S. Federal Building and Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 125708 (Sub-150TA), filed July 21, 1978. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., 425 West 152d Street, East Chicago, IN 46312. Representative: Donald W. Smith, Suite 945, 9000 Keystone Crossing, Indianapolis, IN 46240. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Brick* (except firebrick), from Robertsville, Uhrichsville, and New Lexington, OH, to Jupiter, FL, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Allied Refactories, P.O. Box 185, Robertsville, OH. Send protests to: Lois M. Stahl, Transportation Assistant, Interstate Commerce Commission, Bureau of Operations, 219 South Dearborn Street, Room 1386, Chicago, IL 60604.

MC 126305 (Sub-94TA), filed July 22, 1978. Applicant: BOYD BROS. TRANSPORTATION CO., INC., an Alabama corporation, Route 1, Clayton, AL 36016. Representative: George A. Olsen, Traffic Consultants, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Steel plates, coils, and sheets*, from the facilities of Republic Steel Corp., Gadsden, AL, to points in the States of WV, GA, MS, TN, NC, SC, KY, FL, LA, AR, and VA; and (2) *materials, equipment, and supplies* used in the manufacture or production of iron and steel and iron and steel articles, from points in the States of WV, GA, MS, TN, NC, SC, KY, FL, LA, AR, and VA, to the facilities of Republic Steel Corp., Gadsden, AL, for 180 days. Supporting shipper(s): Republic Steel Corp., Alabama City Station, Gadsden, AL 35901. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 128273 (Sub-310TA), filed July 21, 1978. Applicant: MIDWESTERN DISTRIBUTION, INC., P.O. Box 189, 121 Humboldt Street, Fort Scott, KS 66701. Representative: James W. Muldoon, 50 West Broad Street, Columbus, OH 43215. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are manufactured, processed, distributed, or dealt in, by manufacturers or converters of paper and products (except commodities in bulk) from Chillicothe and Schooleys, OH, to Glendale, Mesa, Phoenix, Pinetop, and Tuscon, AZ; DeQueen, Fayetteville, Fort Smith, Little Rock, North Little Rock, Osceola, Searcy, Springdale, and Van Buren, AR; Bakersfield, Berkeley, Buena Park, Burbank, Canoga Park, Carmichael, Carson, City of Commerce, City of Industry, Compton, Covina, Culver City, Exeter, Fremont, Fresno, Gilroy, Glendale, Hanford, Huntington Beach, Long Beach, Los Alamitos, Los Angeles, Menlo Park, Merced, Miro Loma, National City, North Hollywood, Oakland, Oxnard, Palo Alto, Pasadena, Paso Robles, Porterville, Redwood City, Riverside, Sacramento, San Bernardino, San Carlos, San Diego, San Francisco, San Jose, San Luis Obispo, San Rafael, Santa Fe Springs, Santa Monica, Santee, South San Francisco, Stanton, Stockton, Tustin, Union City, and West Sacramento, CA; Boulder, Colorado Springs, Denver, and Lakewood, CO; Boise, Caldwell, and Lewiston, ID; Algona, Bettendorf, Cedar Rapids, Clinton, Davenport, Des Moines, De Witt, Iowa City, Newton, and Osage, IA; Caney, Cherryvale, Emporia, Fort Scott, Fredonia, Girard, Hutchinson, Kansas City, Lawrence, Leavenworth, Lenexa, Manhattan, Overland Park, Parsons, Pittsburg, Shawnee Mission, Topeka, and Wichita, KS; Arabi, Baton Rouge, Monroe, New Orleans, and Shreveport, LA; Gautier, Olive Branch, Pascaugoula, South Haven, and Tupelo, MS; Aurora, Cape Girardeau, Columbia, Conception, Des Peres, Golden City, Independence, Jefferson City, Kansas City, Kirksville, Marceline, Moberly, North Kansas City, Owenville, St. Joseph, St. Louis, and Springfield, MO; Billings, MT; Grand Island, Lincoln, Norfolk, and Omaha, NE; Las Vegas, Reno, and Sparks, NV; Albuquerque, Carlsbad, Portales, Roswell, and Santa Fe, NM; Fargo, ND; Bartlesville, Dewey, Elk City, Guymon, Lawton, Muskogee, Oklahoma City, Sapulpa, and Tulsa, OK; Beaverton, Medford, North Bend, Portland, Roseburg, St. Paul, and Salem, OR; SD; Abilene, Amarillo, Arlington, Austin, Beaumont, Bryan, Carrollton, Corpus Christi, Dallas, Denison, Denton, El Paso, Ennis, Fort Worth, Galveston, Gladewater, Grand Prairie, Houston,

Johnson City, Laredo, Lubbock, Marlin, Nacogdoches, Orange, Paris, San Angelo, San Antonio, Sequin, Temple, Terrell, Waco, and Wolfe City, TX; Salt Lake City, UT; Bellingham, Kent, Pasco, Renton, Seattle, Spokane, Tacoma, and Tukwila, WA; and Laramie, WY, for 180 days. Supporting shipper(s): The Mead Corp., Mead World Headquarters, Courthouse Plaza Northeast, Dayton, OH 45463. Sent protests to: M. E. Taylor, District Supervisor, Interstate Commerce Commission, 101 Litwin Building, Wichita, KS 67202.

MC 135797 (Sub-131TA), filed July 21, 1978. Applicant: J. B. HUNT TRANSPORT, INC. (a Georgia Corporation), P.O. Box 200, U.S. Hwy. 71, Lowell, AR 72745. Representative: Paul R. Bergant (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plastic articles* (except in bulk) from the facilities owned or utilized by Mobil Chemical Co., Plastics Division at Chicago, IL, to points in the States of MO and KS, and Temple, TX for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Mobil Chemical Co., Plastics Division, Macedon, NY 14502. Send protests to: William H. Land, Jr., District Supervisor, 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 138882 (Sub-108TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Charcoal, charcoal briquets, hickory chips, vermiculite, charcoal lighter fluid, fireplace logs* (compressed sawdust—wax impregnated), *related barbecue items, and materials, equipment, and supplies* used in the distribution of the above-mentioned items, except in bulk, between the facilities of Kingsford Co. located at or near Belle, MO, on the one hand, and, on the other, points in MN, ND, SD, NE, KS, CO, OK, AR, LA, TX, NM, AZ, CA, OR, IA, and IL, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kingsford Co., P.O. Box 1033, Louisville, KY 40201. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-109TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Aluminum ingots*, from the facilities of Keystone Resources Aluminum Division, Greensboro, GA, to Chicago, IL, and its commercial zone; Bedford Heights, Cleveland, Toledo, and Willoughby, OH; Jackson, MI; Pottstown, PA; Stamford, CT; and Henderson, KY; and (2) *aluminum scrap*, from points in CT, NY, NJ, PA, IL, IN, OH, KY, and NC, to the facilities of Keystone Resources Aluminum Division, Greensboro, GA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Keystone Resources, P.O. Box 687, Greensboro, GA 30642. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-110TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Charcoal, charcoal briquets, hickory chips, vermiculite, charcoal lighter fluid, fireplace logs* (compressed sawdust—wax impregnated), *related barbecue items, and materials, equipment, and supplies* used in the sale and distribution of the above-mentioned items, except in bulk, between Jacksonville, TX, on the one hand, and, on the other, points in AZ and CA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kingsford Co., P.O. Box 1033, Louisville, KY 40201. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-111TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Charcoal, wood chips, vermiculite, lighter fluid, and wax-impregnated and compressed sawdust fireplace logs*, from Tucker County, WV, to AL, AR, CT, DE, FL, GA, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, NH, NJ, NY, NC, OH, OK, PA, RI, SC, TN, TX, VT, VA, WV, WI, and DC; and (2) *materials, supplies, and equipment* used in the manufacture of charcoal, wood chips, vermiculite, lighter fluid, and wax-impregnated and compressed sawdust fireplace logs, from points in AL, AR, CT, DE, FL, GA, IL, IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO, NH, NJ, NY, NC, OH, OK, PA, RI, SC, TN, TX, VT, VA, WV, WI, and DC, to Tucker County, WV, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kingsford Co., P.O. Box 1033, Louisville, KY 40201. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-112TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: (1) *Charcoal, charcoal briquets, fireplace logs, wood chips, lighter fluid, spices, sauces, and vermiculite* (except commodities in bulk), from Cotter, AR, to points in the United States except AK and HI; and (2) *materials, supplies, and equipment* used in connection with the commodities described in (1) above, from points in the United States except AK and HI, to Cotter, AR, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kingsford Co., P.O. Box 1033, Louisville, KY 40201. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-113TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Roofing and building materials, and materials* used in the installation and application of such commodities, except commodities in bulk, from the facilities of Bird & Son, Inc., Charleston Heights, SC, to points in FL, for 180 days. Supporting shipper(s): Bird & Son, Inc., Washington Street, East Walpole, MA 02032. Send protests to: Mabel E. Holston,

Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-114TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Charcoal briquets*, from Springfield, OR, to WA, ID, MT, WY, and CA, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): The Kingsford Co., P.O. Box 1033, Louisville, KY 40201. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-115TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Conduit or pipe, cement*, containing asbestos fiber and fittings, from the facilities of Cement Asbestos Products Co. (subsidiary of Asarco, Inc.), at or near Ragland, AL, to points in CT, DE, FL, GA, IL, IN, KY, LA, ME, MD, MA, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, TX, VT, VA, WV, and DC, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Cement Asbestos Products Co., subsidiary Asarco, Inc., 611 Olive Street, Suite 1755, St. Louis, MO 63101. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-116TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, Inc., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Transportation Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Plywood*, from the facilities of furniture Veneers, Inc., located at or near Conway, SC, to Huntingburg and Salem, IN, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Furniture Veneers, Inc., P.O. Box 504, Conway, SC 29526. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 138882 (Sub-150TA), filed July 22, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: George A. Olsen, Traffic Consultant, P.O. Box 357, Gladstone, NJ 07934. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber and plywood*, from the facilities of Scotch Lumber Co., and Scotch Plywood Co., located at Fulton, AL, to points in FL, GA, IL, IN, IA, LA, KY, MI, MN, MS, MO, NC, OH, SC, SD, TN, TX, and WI, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Scotch Lumber Co., Fulton, AL 36446. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 141774 (Sub-14TA), filed July 22, 1978. Applicant: R & L TRUCKING CO., INC., an Alabama corporation, 105 Rocket Avenue, Opelika, AL 36801. Representative: Robert E. Tate, Registered Practitioner, P.O. Box 517, Evergreen, AL 36401. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Insulating materials, mineral wool*, from the facilities of Rock Wool Manufacturing Co., Leeds, AL, to points in FL, GA (on and south of U.S. 80), MS, TN (on and west of Interstate 65), KY, and New Orleans, LA, and its commercial zone, for 180 days. Supporting shipper(s): Rock Wool Manufacturing Co., 500 Thornton Avenue NE, Leeds, AL 35094. Send protests to: Mabel E. Holston Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203

MC 143844 (Sub-2TA), filed July 21, 1978. Applicant: DOUG GRANT TRUCK TRANSPORTATION, INC., P.O. Drawer GG, Eureka, CA 95501. Representative: Earle V. White, White & Southwell, 2400 SW. Fourth Avenue, Portland, OR 97201. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Woodpulp*, baled, from Samoa, CA, to Salem, OR, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Louisiana-Pacific Corp., Samoa, CA 95564. Send protests to: District Supervisor A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 144162 (Sub-2TA), filed July 21, 1978. Applicant: TIME CONTRACT CARRIERS, INC., 27301 Camp Plenty Road, Canyon Country, CA 91351. Representative: Milton W. Flack, 4311 Wilshire Boulevard, Suite 300, Los Angeles, CA 90010. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Safes, vaults, and insulated files;* and (2) *parts, accessories, and components* of commodities described in (1) above, from Lafayette, IN, to points in WA and OR, for 180 days. Supporting shipper(s): Richard P. Vaughan & Associates, Inc., 813 Thomas Avenue SW., Renton, WA 98055. Send protests to: Irene Carlos, Transportation Assistant, Interstate Commerce Commission, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 145009 (Sub-1TA), filed July 22, 1978. Applicant: WALTER SHORE, P.O. Box 749, Winfield, AL 35594. Representative: same as above. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Lumber and lumber products*, from Haleyville, AL, to points in TN, MO, IA, MN, WI, MI, IL, IN, OH, PA, NY, WV, KY, MS, and LA, for 180 days. Supporting shipper(s): Fullco Lumber Co., P.O. Box 617, Haleyville, AL 35565. Send protests to: Mabel E. Holston, Transportation Assistant, Bureau of Operations, Interstate Commerce Commission, Room 1616, 2121 Building, Birmingham, AL 35203.

NOTE.—Applicant will also operate as a private carrier. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority.

MC 145039 (Sub-1TA), filed July 20, 1978. Applicant: B & H PIGGYBACK SERVICE, INC., P.O. Box 4096, North Station, Winston-Salem, NC 27105. Representative: J. R. Hiatt, P.O. Box 4096, Winston-Salem, NC 27105. Authority sought to operate as a *common carrier*, by motor vehicle, over irregular routes, transporting: *Piggyback shipments*, having a prior or subsequent movement by rail over irregular routes between Winston-Salem, NC, and points within 118-mile radius of Winston-Salem, NC, for 180 days. Applicant has also filed and underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): There are approximately four statements of support attached to the application which may be examined at the Interstate Commerce Commission in Washington, D.C., or copies thereof which may be examined at the field office named below. Send protest to: Terrell Price, District Supervisor, 800 Briar Creek Road, Room CC516, Mart Office Building, Charlotte, NC 28205.

MC 145099 (Sub-1TA), filed July 21, 1978. Applicant: MARLOR ENTERPRISES, LTD., 2950 Altamont Crescent, West Vancouver, BC, Canada V7V 1C3. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Lumber*, from the ports of entry between the United States and Canada at or near Blaine, Sumas, Oroville, Ferry, and Danville, WA, Eastport, ID, and Eureka, MT, to points in AZ, CA, NV, and TX, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days of operating authority. Supporting shipper(s): Marlor Industries, Ltd., 2950 Altamont Crescent, West Vancouver, BC, Canada V7V 1C3. Send protests to: Hugh H. Chaffee, District Supervisor, Bureau of Operations, ICC, 858 Federal Building, Seattle, WA 98174.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-27335 Filed 9-28-78; 8:45 am]

sunshine act meetings

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409), 5 U.S.C. 552b(e)(3)

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[6320-01]

1

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 9:30 a.m., September 28, 1978.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT: Oral Argument—Docket 30356, Transcontinental Low Fare Route Proceeding.

STATUS: Open.

PERSON TO CONTACT:

Phyllis T. Kaylor, the Secretary, 202-673-5068.

SUPPLEMENTARY INFORMATION: Due to a clerical error, this notice was not available 7 days in advance. So that the Board can meet to hear this oral argument at the scheduled time, the following members have voted that agency business requires that the Board meet on less than 7 days' notice and that no earlier announcement of this meeting was possible:

Chairman, Alfred E. Kahn
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey

[S-1976-78 Filed 9-27-78; 11:38 am]

[6320-01]

2

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 1 p.m., September 29, 1978.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

1. Ratification of items adopted by notation.

2. Docket 29044, Part 252 of the Board's Economic Regulations—(1) Final rule on seating segregation; (2) proposed rules on further amendments (Memo 7323-E, OGC)

3. Docket 32610, Belize Airways, Ltd., application for amendments of foreign air carrier permit to serve additional U.S. terminals per Bermuda II (Memo 7207-C, BIA, OGC).

4. The Internal Revenue Service has requested access to Bureau of Consumer Protection investigatory files, some of which contain materials secured through section 407(e) of the Federal Aviation Act inspection authority (Memo 8199, BCP).

5. Dockets 31129 and 32910, Commuter Airlines' exemptions to operate large aircraft (BPDA, OGC, BCP).

6. Dockets 29983 and 30390, Application of Eastern for realignment for Route 5: Allegheny's motion to consolidate its application for certificate amendment for Route 97 (Memo 8198, BPDA).

7. Docket 31496, Piedmont's motion for hearing on Miami Entry Authority (Memo 8160, BPDA).

8. Docket 32696 and 32697, Frontier's application for certificate authority to serve Redding, Calif., and Petition for an Order to Show Cause; Frontier's request for exemption authority serve Redding (Memo 8194 BPDA, OGC).

9. Docket 31319, Dan-Air Services, Ltd.—Certificate amendment to permit charter cargo operations for air freight forwarders—finalization of show cause order (Memo 7923-A, BPDA, OGC, BIA).

10. Proposed industry letter concerning charters to the Super Bowl (Memo 8185, BPDA, BCP, OGC).

11. Docket 30332, Petition for reconsideration of Order 78-4-78 denying IATA Resolution 511a to ban C.O.D. shipment of live animals (Memo 7344-C, BPDA).

12. Docket 30777, IATA agreement proposing piece-based baggage system between the United States and various South American countries (Memo 8195, BPDA, BIA).

13. Docket 25875, Termination of proposed rulemaking which would have amended part 399 by establishing minimum rate guidelines for charter service between the United States and Europe (Memo 8190, OGC, BIA, BPDA).

14. Dockets 32327, 33361, 33362, and 33363, *Former Large Irregular Air Carrier Investigation* (Memo 7690-E, 7909-F, OGC).

15. Docket 31827, *In the Matter of Sidney S. Sperling* v. *Southern Airways, Inc.*, petition for review of Bureau of Consumer Protection dismissal of "smoking" complaint against Southern (Memo 8192, OGC).

16. Docket 30790, *United States-Benelux Low-Fare Proceeding* (Memo 7978-D, 7978-E, 7978-F).

17. Docket 28366, *Denver-Alaska Service Investigation; San Francisco-Reno-Albuquerque-Texas Service Investigation*, Docket 32710—Orders on Reconsideration (Memo 8193, OGC).

18. Docket 32376, *San Antonio-Denver Route Proceeding*, Order on reconsideration (Memo 7751-B, OGC).

19. Docket 32785, Amendment of part 241, as proposed in EDR-357, for accounting for troubled debt restructurings, prior period adjustments, and forward exchange contracts (Memo 7979-A, BAS).

20. Docket 23287, Air Freight Forwarders' Charters Investigation (Memo 7189-A, OGC, BCP, BIA).

21. Revision of record retention requirements (Memo 8197, BAS).

STATUS: Open.

PERSON TO CONTACT:

Phyllis T. Kaylor, the Secretary, 202-673-5068.

[S-1977-78 Filed 9-27-78; 11:38 am]

[3410-05]

3

COMMODITY CREDIT CORPORATION.

CANCELLATION OF MEETING SCHEDULED FOR SEPTEMBER 29, 1978.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Vol. 43, No. 185, September 22, 1978, page 43083.

MEETING RESCHEDULED FOR OCTOBER 26, 1978, 3 P.M.

PLACE: Room 218-A, Administration Building, U.S. Department of Agriculture.

SUBJECT: Agenda to be announced at a later date.

FOR FURTHER INFORMATION CONTACT:

Bill Cherry, Acting Secretary, Commodity Credit Corporation, Room 202-W, Administration Building, U.S. Department of Agriculture, Washington, D.C. 20013, telephone 202-447-7583.

[S-1983-78 Filed 9-27-78; 11:38 am]

[6351-01]

4

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 10 a.m., October 3, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 5th floor hearing room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Baseline Calendar fiscal year 1979.
Request of the New York Coffee and Sugar Exchange for an extension in filing its § 1.50 report on coffee.
Petition for the Commission to amend its rules on speculative sales.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1979-78 Filed 9-27-78; 11:38 am]

[6351-01]

5

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 11:30 a.m., October 3, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 5th floor hearing room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

Enforcement Matters/Applications for registration as associated persons of a futures commission merchant.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1980-78 Filed 9-27-78; 11:38 am]

[6351-01]

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 11 a.m., October 6, 1978.

PLACE: 2033 K Street NW., Washington, D.C., 8th floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED: Market surveillance meeting.

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314.

[S-1981-78 Filed 9-27-78; 11:38 am]

[6570-06]

7

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: S-1929-78, S-1956-78, and S-1965-78.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 1:30 p.m. (eastern time), Tuesday, September 26, 1978.

CHANGE IN THE MEETING: The following matter was postponed from the open portion of the meeting to the closed portion:

Contract with National Academy of Sciences on Wage Comparability Study.

A majority of the entire membership of the Commission determined by recorded vote that the business of the Commission required this change and that no earlier announcement was possible.

In favor of change.—Eleanor Holmes Norton, Chair; Daniel E. Leach, Vice Chair; and Ethel Bent Walsh, Commissioner.
Opposed.—None.

CONTACT PERSON FOR MORE INFORMATION:

Marie D. Wilson, Executive Officer, Executive Secretariat, at 202-634-6748.

This notice issued September 26, 1978.

[S-1984-78 Filed 9-27-78; 3:44 pm]

[6570-06]

8

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.

TIME AND DATE: 9:30 a.m. (eastern time), Tuesday, October 3, 1978.

PLACE: Chairman's Conference Room, No. 5240, on the fifth floor of the Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

STATUS: Part will be open to the public and part will be closed to the public.

MATTERS TO BE CONSIDERED:

Open to the public:

1. Freedom of Information Act Appeal No. 78-7-FOIA-150, concerning a request by a party filing a charge of discrimination for access to the investigative file after his right to bring a title VII civil action has expired.
2. Freedom of Information Act Appeal No. 78-7-FOIA-134, concerning a request by a party filing a charge of discrimination for access to an investigative file concerning a charge against the same employer filed by another person.
Proposed procedures to implement Executive Order 12044 and final report required by that order.
4. Proposed EEO complaint appeals procedures for Federal Employees.
5. Report on Commission Operations by the Executive Director.

Closed to the public:

Litigation Authorization; General Counsel Recommendations: Matters closed to the public under the Commission's regulations at 29 CFR 1612.13.

NOTE.—Any matter not discussed or concluded may be carried over to a later meeting.

CONTACT PERSON FOR MORE INFORMATION:

Marie D. Wilson, Executive Officer, Executive Secretariat, at 202-634-6748.

This notice issued September 26, 1978.

[S-1985-78 Filed 9-27-78; 3:44 pm]

[6715-01]

9

FEDERAL ELECTION COMMISSION.

DATE AND TIME: Wednesday, October 4, 1978, at 10 a.m.

PLACE: 1325 K Street NW., Washington, D.C.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Audit Reports, Compliance, Personnel.

* * *

DATE AND TIME: Thursday, October 5, 1978, at 10 a.m.

STATUS: Portions of this meeting will be open to the public and portions will be closed.

MATTERS TO BE CONSIDERED:

Portions open to the public:

Setting of dates for future meetings.
Correction and approval of minutes.
Advisory Opinions: AO 1978-65; AO 1978-72.
Appropriations and budget.
Earmarked contributions.
Presidential campaign disclosure form.
Pending legislation.
Pending litigation.
Liaison with other Federal agencies.
Reports from division heads.
Loans by candidates to committees.
Classification actions.
Routine administrative matters.
Computer contract procurement.

Portions closed to the public:

Any matters not concluded on Wednesday, October 4, 1978.

PERSON TO CONTACT FOR INFORMATION:

Mr. David Fiske, Press Officer, telephone 202-523-4065.

MARJORIE W. EMMONS,
Secretary to the Commission.

[S-1987-78 Filed 9-27-78; 3:44 pm]

[6740-02]

10

SEPTEMBER 27, 1978.

FEDERAL ENERGY REGULATORY COMMISSION.

TIME AND DATE: 10 a.m., October 4, 1978,

PLACE: 825 North Capitol Street, NE., Washington, D.C., Room 9306.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

NOTE.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION:

Kenneth F. Plumb, Secretary, telephone 202-275-4166.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda. However, all public documents may be examined in the Office of Public Information.

GAS AGENDA—164TH MEETING, OCTOBER 4, 1978, REGULAR MEETING

CAG-1. Docket No. RP78-79, United Gas Pipe Line Co.
CAG-2. Docket No. RP73-8 (PGA No. 78-9), North Penn Gas Co.
CAG-3. Docket Nos. RP77-54 and RP77-55, Arkansas Louisiana Gas Co.
CAG-4. Docket No. RI78-71, American Petrofina Co. of Texas, et al.
CAG-5. Docket Nos. G-7115, et al., Coastal States Gas Producing Co., et al.
CAG-6. Docket Nos. G-11860, et al., Mobil Oil Corp., et al.
CAG-7. Docket Nos. G-5766, et al., Continental Oil Co., et al.
CAG-8. Docket No. CI77-813, Oil Development Co. of Texas.
CAG-9. Docket No. CI78-176, W.R.W. Enterprises, Inc.
CAG-10. Docket Nos. CI77-563, et al., Shell Oil Co., et al.
CAG-11. Docket Nos. CS78-401, et al., United Co., et al.
CAG-12. Docket Nos. CS78-184, et al., P.H.N. Ltd., et al.
CAG-13. Docket Nos. CS72-1169, et all, Bobby Joe Manziel, et al.
CAG-14. Docket No. CP78-406, Transcontinental Gas Pipe Line Corp.
CAG-15. Docket No. CP77-21, Columbia Gulf Transmission Co., Tennessee Gas Pipeline Co., a division of Tenneco Inc.
CAG-16. Docket No. CP78-212, Transcontinental Gas Pipe Line Corp.
CAG-17. Docket No. CP77-378, Northwest Pipeline Corp.
CAG-18. Docket No. CP75-14, et al., Algonquin LNG, Inc., et al.

I. PIPELINE RATE MATTERS

RP-1. Docket No. RP74-41, Texas Eastern Transmission Corp.
RP-2. Docket Nos. RP73-3 (PGA78-3), et al., Transcontinental Gas Pipe Line Corp.
RP-3 Docket No. RP76-31, Louisiana-Nevada Transit Co.

II. PIPELINE CERTIFICATE MATTERS

CP-1. Docket No. CP77-38, Tennessee Gas Pipeline Co., division of Tenneco Inc., National Fuel Gas Supply Corp.
CP-2 Docket No. CP76-509, Transwestern Pipeline Co., Docket No. CP76-516, Western Gas Interstate Co.
CP-3. Docket No. CP77-273, Arkansas Louisiana Gas Co., Docket No. CP77-338, Lone Star Gas Co.
CP-4 Docket No. CP77-176, Kansas-Nebraska Natural Gas Co., Inc.

MISCELLANEOUS AGENDA—164TH MEETING, OCTOBER 4, 1978, REGULAR MEETING

CAM-1. (A) Docket No. RA78-5, Young Refining Corp. (B) Docket No. RA78-1, Lenday-Thagard Oil Co. (C) Docket No. RA78-6, Dorchester Gas Corp. (D) Docket No. RA78-4, Bayou State Oil Corp.
M-1. Docket No. RM78-10. Procedures for review by the Federal Energy Regulatory Commission of remedial orders issued by the Secretary of Energy.

POWER AGENDA—164TH MEETING, OCTOBER 4, 1978, REGULAR MEETING

CAP-1. Docket Nos. ER78-293, ER78-298, and ER78-302, Illinois Power Co.
CAP-2. Docket No. ER78-602, Indiana & Michigan Electric Co. and Illinois Power Co.
CAP-3. Docket No. ER78-603, Southern California Edison Co.
CAP-4. Docket No. ER78-605, New England Power Co.
CAP-5. Docket No. E-8242, Public Service Co. of Oklahoma.
CAP-6. Project No. 2763, City of Golden, Colo., and Vidler Tunnel Water Co. Project No. 2773, Oak Creek Power Co. Project No. 2779, Colorado River Water Conservation District.

I. ELECTRIC RATE MATTERS

ER-1. Docket No. ER78-507, Public Service Co. of Colorado.
ER-2. Docket No. ER78-478 et al., Florida Power & Light Co.
ER-3. Docket No. ER76-539, Missouri Power & Light Co.
ER-4. Docket No. E-9520, Illinois Power Co.
ER-5. Docket No. ER77-533, Louisiana Power & Light Co.
ER-6. Docket No. ER77-313, Union Light, Heat & Power Co.
ER-7. Docket No. ER78-813, Jersey Central Power & Light Co.

KENNETH F. PLUMB,
Secretary.

[S-1986-78; Filed 9-27-78; 3:44 pm]

[6720-01]

11

FEDERAL HOME LOAN BANK BOARD.

TIME AND DATE: 9:30 a.m., October 3, 1978.

PLACE: 1700 G Street NW., sixth floor, Washington, D.C.

STATUS: Open meeting.

CONTACT PERSON FOR MORE INFORMATION:

Franklin O. Bolling, 202-377-6677.

MATTERS TO BE CONSIDERED:

Application for Amendment of Charter-Change of Name—Chicago Heights Federal Savings & Loan Association, Chicago Heights, Ill.
Consideration of Revision of Federal Home Loan Bank Regulations.
Consideration of Merger Application—Franklin Savings & Loan Association, Wausau, Wis. into Security Savings & Loan Association, Milwaukee, Wis.
Agency Office Application—Home Federal Savings & Loan Association of San Diego, San Diego, Calif. (Fair Oaks).
Application for Extension of Time for Relocation of a Branch Office—Illini Federal Savings & Loan Association, Fairview Heights, Ill.
Branch Office Application—Washington Federal Savings & Loan Association of Miami Beach, Miami Beach, Fla.
Branch Office Application—Smithville Federal Savings & Loan Association, Smithville, Tex.
Application for Permission to Change Office Location—Florida Federal Savings & Loan Association, St. Petersburg, Fla.
Agency Office Application—Home Federal Savings & Loan Association of San Diego, San Diego, Calif. (Orange County).
Agency Office Application—Home Federal Savings & Loan Association of San Diego, San Diego, Calif. (Los Angeles).
Satellite Office Application—Franklin Federal Savings & Loan Association, St. Petersburg, Fla.
Branch Office Application—West Coast Federal Savings & Loan Association, San Mateo, Calif.
Application for Proposed Merger—Alvin Progressive Federal Savings & Loan Association, Philadelphia, Pa., into Prudential Savings Association, Philadelphia, Pa.
Application for Change of Office Location—Hollywood Federal Savings & Loan Association, Hollywood, Fla.
Application to Acquire Shaker Savings Association, Shaker Heights, Ohio, and Request for Authority to Incur Indebtedness—Ohio Savings Financial Corp., Cleveland, Ohio.
Application for Authority to Acquire State Savings & Loan Association, Lubbock, Tex., and for Authority to Assume Debt—State Management, Inc., Lubbock, Tex.
Consideration of report to the Bank Board on CRA proposed regulations and related matters.

No. 186, September 26, 1978.

RONALD A. SNIDER,
Assistant Secretary.

[S-1982-78 Filed 9-27-78; 11:38 am]

[7600-01]

12

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: September 26, 1978, page 43617.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 9:30 a.m., October 4, 1978.

CHANGES IN THE MEETING: To 1 p.m., October 12, 1978.

Dated: September 26, 1978.

[S-1978-78 Filed 9-27-78; 11:38 am]

[8240-01]

13

UNITED STATES RAILWAY ASSOCIATION.

TIME AND DATE: 9 a.m., October 4, 1978.

PLACE: Board Room, Room 2-500, fifth floor, 955 L'Efant Plaza North SW., Washington, D.C. 20595.

STATUS: Parts of this meeting will be open to the public. The rest of the meeting will be closed to the public.

MATTERS TO BE CONSIDERED BY THE BOARD OF DIRECTORS OR ITS EXECUTIVE COMMITTEE:

Portions closed to the public (9 a.m.):

1. Consideration of internal personnel matters.
2. Review of ConRail proprietary and financial information for monitoring and investment purposes.
3. Review of Delaware & Hudson Railway Co. proprietary and financial information for monitoring and investment purposes.
4. Review of Missouri-Kansas-Texas Railroad Co., proprietary and financial information.
5. Litigation report.

Portions open to the public (11 a.m.):

6. Approval of minutes of the September 7 and 21, 1978, meetings of the Executive Committee of the Board of Directors.
7. Consideration of fiscal year 1979 Merit/Salary Policy.
8. Consideration of advances to D&H.
9. Report on ConRail monitoring.
10. Consideration of ConRail waiver requests.
11. Consideration of ConRail fourth quarter 1978 Investment Commitment.
12. Consideration of ConRail drawdown request for October 1978.
13. Status of 211(h) loan program.
14. Contract actions (extensions and approvals).

CONTACT PERSON FOR MORE INFORMATION:

Alex Bilanow, 202-426-4250.

[S1975-78 Filed 9-27-78; 11:38 am]

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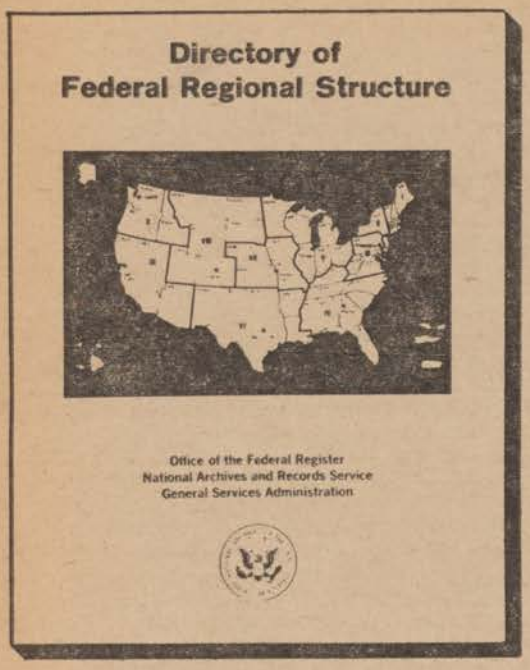

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

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HUMAN AND VETERINARY DRUGS

Good Manufacturing Practices and Proposed Exemptions for Certain OTC Products

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—DRUGS: GENERAL

[Docket No. 75N-0339]

HUMAN AND VETERINARY DRUGS

Current Good Manufacturing Practice in Manufacture, Processing, Packing, or Holding

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the FDA regulations that set forth current good manufacturing practice (CGMP) for human and veterinary drug products. The amendments update present regulations in light of current technology for drug manufacturing and delineate requirements more specifically than do the present regulations. Although some of the provisions in these amendments represent requirements not specifically included in the existing CGMP regulations, in many instances the revisions are practices that have been considered implicit in the regulations or are at least considered by most manufacturers to be desirable requirements for their own operations.

Under the Federal Food, Drug, and Cosmetic Act, a drug is deemed to be adulterated unless the methods used in its manufacture, processing, packing, and holding, and the facilities and controls used therefor, conform to current good manufacturing practice so that the drug meets the safety requirements of the act and has the identity and strength and meets the quality and purity characteristics that it is represented to have. The regulations are being updated and made more explicit, and therefore less subject to varying interpretations, to assure that all members of the drug industry are made aware of the level of performance expected of them to be in compliance with the act.

EFFECTIVE DATE: March 28, 1979.

FOR FURTHER INFORMATION CONTACT:

Clifford G. Broker (HFD-323) (301-443-5307), or Robert J. Rice, Jr., (HFD-30) (301-443-5220), Bureau of Drugs, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857.

SUPPLEMENTARY INFORMATION: In the FEDERAL REGISTER of February 13, 1976 (41 FR 6878), the Commissioner of Food and Drugs proposed to revise the CGMP regulations, Parts 210 and 211 (21 CFR Parts 210 and 211), issued under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(B)), to update them in light of current technology and to adopt more specific requirements to assure the quality of finished drug products. Because of the nature and extent of the proposed revisions, the Commissioner allowed until June 14, 1976, for interested persons to submit comments.

The Commissioner received comments from 168 respondents totaling approximately 2,000 pages. These comments represent many interests—individual consumers; nonprofit institutions or associations; health-care departments of hospitals, colleges, and universities; State and foreign health-care organizations; domestic and foreign drug manufacturers, repackers, and distributors; consultants to the drug industry; drug equipment manufacturers; and numerous trade and professional associations representing manufacturers, repackers, distributors, consulting engineers, and professionals in the health-care system.

In general, the comments supported the Commissioner's concern for the availability of uniformly high quality drug products. Consumers, in particular, expressed strong support for the proposed revisions, especially the provisions for expiration dating of pharmaceuticals. A majority of drug manufacturers agreed with many of the proposed revisions, but objected to others. A few manufacturers objected to most of the proposal.

The Commissioner is pleased to note that where differences existed, many interested persons furnished alternative wording and justification in support of such alternatives. The Commissioner has carefully considered every comment and all suggested alternatives. The final regulation, set forth below, adopts a number of the recommendations submitted. Certain other recommendations, not adopted at this time, may be considered in any future proposed revisions.

During the past several years, the FDA has issued a number of FEDERAL REGISTER documents relating to CGMP regulations, specifically Parts 210 and 211. The following summary will help clarify the status of these various documents.

1. A proposal on returned and salvaged drug products appeared in the FEDERAL REGISTER of January 16, 1975 (40 FR 2822) and was reproposed as § 211.208 (21 CFR 211.208) in the FEDERAL REGISTER of February 13, 1976 (41 FR 6870). Comments on both proposals were reviewed and considered in preparing the final regulations set forth in Part 211 below.

2. A proposal on CGMP regulations for human and veterinary drugs appeared in the FEDERAL REGISTER of February 13, 1976 (41 FR 6878). That proposal is the basis for the subject final regulations and included proposed revisions in §§ 201.17, 207.3, 207.20, and Parts 210 and 211, and revocation of § 229.25.

3. A final regulation in the FEDERAL REGISTER of April 23, 1976 (41 FR 16932) amended Part 211 (CGMP regulations) by eliminating reference to glass-fiber filters. It, therefore, eliminated the need for further comments on the February 13, 1976, proposal regarding such filters because all references to glass fiber-containing filters would be deleted from the final regulation.

4. A proposal on CGMP regulations for large volume parenteral drug products (LVP) for human use was published in the FEDERAL REGISTER of June 1, 1976 (41 FR 22202). The proposal would add a new Part 212. Comments were due by September 29, 1976 and are under review.

5. A request for comments and information regarding small volume parenteral drug products (SVP) was published in the FEDERAL REGISTER of June 1, 1976 (41 FR 22219), and the time for submitting comments was extended to October 29, 1976 by notice in the FEDERAL REGISTER of September 10, 1976 (41 FR 38540). Comments are being reviewed, and a specific proposal may be published in the future.

The comments and recommendations regarding the January 16, 1975 and February 13, 1976 proposals, the April 23, 1976 amendment to the latter proposal, and the Commissioner's conclusions concerning them are set out below.

TABLE OF CONTENTS FOR PREAMBLE

I. General Comments (paragraphs 1 to 12).

II. Terminology and Language in these Regulations (paragraphs 13 to 18).

III. Amendments Regarding Placement of Expiration Date on Drug Product Labels (paragraphs 19 to 27).

IV. Amendments Regarding Drug Listing and Establishment Registration Requirements for Drug Product Salvaging Operations (paragraphs 28 to 32).

V. Legal Status of CGMP Regulations (paragraphs 33 to 41).

VI. Applicability of CGMP Regulations; Exemptions (paragraphs 42 to 49).

VII. Definitions (paragraphs 50 to 88).

VIII. Organization and Personnel (paragraphs 89 to 126).

IX. Buildings and Facilities (paragraphs 127 to 164).

X. Equipment (paragraphs 165 to 198).

XI. Control of Components and Drug Product Containers and Closures (paragraphs 199 to 262).

XII. Production and Process Controls (paragraphs 263 to 310).
XIII. Packaging and Labeling Control (paragraphs 311 to 373).
XIV. Holding and Distribution (paragraphs 374 to 379).
XV. Laboratory Controls (paragraphs 380 to 422).
XVI. Records and Reports (paragraphs 423 to 500).
XVII. Returned and Salvaged Drug Products (paragraphs 501 to 517).
XVIII. CGMP for Certain Other Drug Products (paragraph 518).

I. General Comments

1. Many comments were received regarding the need for the proposed changes in the CGMP regulations. A number of comments from individual consumers, a State consumer services organization, and a national association of health-care professionals strongly favored new or revised regulations that would improve the level of assurance that marketed drug products meet high quality standards. Many other comments, particularly from manufacturers and trade associations, generally supported the desirability of CGMP regulations, but objected to specific provisions of the proposal and questioned whether a favorable cost-benefit ratio justified implementing some of the proposed provisions. But some manufacturers, particularly smaller firms, objected to the proposed changes, maintaining that drug quality would not be improved by the proposed changes and that the costs outweigh any benefits.

The need and rationale for an overall revision and for specific changes in the CGMP regulations are discussed at length in the preamble to the February 13, 1976 proposal. Briefly summarizing this discussion, the technological advances and the general upgrading of drug quality assurance by most manufacturers since the CGMP regulations were promulgated in 1963 and last updated in 1971 mean that the "current good manufacturing practice" reflected in the existing regulations are no longer "current" in many respects and are not suited to current manufacturing techniques. In addition, many requirements prompted questions about interpretation, vagueness, and omissions. The proposal was intended to solve many of these problems. Interested persons were urged to review the proposal carefully, to identify any areas that might require clarification or modification, and to submit reasoned comments with suggested alternative language. The period provided for public comment was 120 days instead of the usual 60 days because of the length of the proposal; the novel, controversial, or complex nature of some of the proposed provisions; and the desire to give affected persons ample time for review and preparation of extensive comments.

Having reviewed the preamble of the February 13, 1976, proposal and the extensive comments, the Commissioner is satisfied that an updating of the CGMP regulations is necessary and desirable. Therefore, most of the February 13, 1976, proposal has been adopted, but with numerous textual changes, many of which are based upon alternative language suggested in the comments. In evaluating each comment, the Commissioner considered whether drug product quality would be assured, compromised, or unaffected by the adoption or deletion of a regulation, as well as whether it reflected a current practice in the industry and its benefits appeared to outweigh its costs. The Commissioner is promulgating those regulations embodying contemporary practices that will maintain or improve the quality of pharmaceuticals without imposing unreasonable or excessive costs or other burdens on manufacturers. Modifications were adopted, or decisions were made not to finalize particular aspects of the proposal, in order to add flexibility for manufacturers, to relieve or eliminate unjustified cost burdens, or to clarify the requirements, without adversely affecting the best interests of the consumer.

The agency has completed a detailed cost analysis based on information submitted by interested persons who commented on the economic impact assessment of the proposal. This issue is discussed in a revised economic impact assessment available at the office of the Hearing Clerk, Food and Drug Administration. For the reasons set forth in the agency's economic impact assessment, it is believed that this final regulation will not cause major economic impact, as defined by Executive Order 11821 (as amended by Executive Order 11949), and OMB Circular A-107.

2. A number of comments said the proposed CGMP regulations would impose rigid and inflexible standards that would curtail progress and discourage technological innovations. Others said the proposed regulations were so detailed that sound judgment by the manufacturers and by inspecting FDA investigators could not be used.

The Commissioner is keenly aware that the general CGMP regulations must apply to a wide variety of drug products. Therefore, the CGMP regulations in Part 211 are intended to be general enough to be suitable for essentially all drug products, flexible enough to allow the use of sound judgment and permit innovation, and explicit enough to provide a clear understanding of what is required. The agency has received numerous inquiries requesting clarification of certain provisions, and it sought to remove ambiguities by this revision. In finalizing these revisions, the Commissioner has considered past experience, the purposes of the CGMP regulations, the need to balance specificity and clarity with flexibility in attaining these purposes, and the comments received in response to the proposal. A number of changes have been made in these final regulations to reflect the broad applicability of, to allow flexibility in, and to encourage innovation within the CGMP regulations. The agency does intend to issue more specific CGMP regulations for unique classes of products as one means of clarifying these regulations. The Commissioner welcomes suggestions and petitions from interested persons who find deficiencies, excessive burdens, or inflexibility in these regulations and who identify innovative and more efficient ways to achieve the goals of these regulations.

3. A number of comments addressed the so-called "how to" versus the "what" argument; that is, the proposed CGMP regulations describe "how" a particular requirement should be achieved rather than specifying "what" it is that is to be achieved. Many comments recommended that the regulations establish only objectives or specifications and allow each manufacturer to determine the best method of attaining the objective or meeting the specification. For example, one comment proposed that FDA require positive identification of a person rather than specifying that a signature be used—this would allow use of other means of identifying a person, such as an identifying number or initials.

The Commissioner believes that, with relatively few exceptions, the CGMP regulations do describe "what" is to be accomplished and provide great latitude in "how" the requirement is achieved. For example, written records and procedures are required, but FDA will recognize as satisfactory any reasonable format that achieves the desired results. Because of the need for uniformity in certain areas of the CGMP regulations that have presented problems in the past, however, there are some instances where it is desirable to specify the manner in which requirements are to be accomplished. In promulgating these regulations, the Commissioner carefully reconsidered the need for such specificity where it appears and adopted only those specific requirements that are fully justified.

4. One comment, filed by an FDA employee, recommended that self-inspection and performance auditing programs within the industry be a requirement under the CGMP regula-

tions to assure the reliability of drug products and to prevent release of defective products.

The Commissioner finds that the concept of self-inspection and performance auditing has considerable merit. The pharmaceutical industry has made great efforts to develop self-evaluation programs, frequently using a team of inspectors composed, at least in part, of people from outside the area or firm being audited. The scope, elements, and intensity of such programs, however, vary from elaborate detailed audits to rather superficial inspections conducted perhaps once a year. The agency has considered such programs in the past, but has concluded that the essential elements of a beneficial program have not yet been sufficiently defined or tested. Moreover, because of the significant impact that a requirement for self-inspection would have on the industry and because only one comment regarding self-inspection was received, the Commissioner concludes that further public discussion is desirable before a specific proposal or regulation is issued.

5. One comment suggested that a product defect surveillance and reporting system requirement similar to the system developed and operated by the United States Pharmacopeia (U.S.P.) be a part of the CGMP regulations. The suggestion would require full participation by manufacturers, rather than voluntary participation, in a system of identifying defective products, removing them from the market, and investigating the cause of the defect.

The Commissioner notes that the Drug Product Defect Reporting System maintained by U.S.P. is designed to identify drug product complaints from various sources other than the manufacturer, such as pharmacies and hospitals, and to facilitate transmission of this information to the manufacturer and to FDA. The value of such a reporting system is in its broad source of information. The CGMP regulations in part 211, however, apply only to manufacturers of drug products. Section 211.198 (21 CFR 211.198) addresses the handling of reports to the manufacturer about drug product defects and requires that manufacturers investigate complaints that may have a bearing on drug product quality. Such information is subject to review by FDA.

6. Comments regarding the effect of these regulations on employee motivation were received from several interested persons. While generally approving the technical aspects of the proposal, these comments expressed concern that employee morale may be stifled because of the "close supervision" or "independent verification" of their work mandated by some of the proposed requirements. The comments also expressed concern about the availability of qualified personnel in the health-care system and the ability of the industry to attract such qualified persons for relatively unimaginative duties. They suggested that the use of a different instrument in the checking procedure would, in some instances, offer a better chance of detecting an error than would a system that relies upon independent verifications by different persons using the same instrument.

The Commissioner recognizes that employee interests and motivation play a major role in assuring drug product quality, as described in the preamble discussion for the proposed § 211.25, relating to employee training, for example. Good employee morale and work motivation are highly desirable in any work situation. Because of potential employee resentment of an intensive "check system," the Commissioner has considered alternatives and the consequences of no independent verification. The requirement for verification applies to functions that involve human judgment and consequently are susceptible to human error. The results of such errors, if undetected and uncorrected, can include, for example, improper formulations and improper release of drug products because of incorrect laboratory calculations. Independent verification is generally considered a "current" practice, not only in the drug industry but elsewhere, as a way to reduce the risk of human error. The intent of such a check is to verify that the procedure or work was performed. It is a necessary function in the manufacture of drug products and is already required in the existing CGMP regulations. The Commissioner believes that, while employees may not always welcome independent verification, most accept it as a condition of their particular assignments. Given the possible serious consequences of errors, the "check system" requirement does not seem to be an unjustified burden and, if properly explained, should not be perceived by employees negatively.

The use of separate instruments, where practicable, as an adjunct to independent verification by a second person, is a procedure that has merit. The Commissioner encourages the use of such a procedure, but has concluded that a separate instrument for independent measurements would be a costly and unnecessary requirement in the CGMP regulations. These regulations separately mandate an equipment calibration and maintenance program to assure proper performance and safeguard equipment accuracy.

7. Several comments indicated a general interest in bioavailability and bioequivalence requirements for drug products. Because of the importance of bioavailability and bioequivalence to safe and effective use of drug products, these comments encouraged FDA to issue regulations establishing necessary requirements to assure this type of product quality as soon as possible.

The Commissioner advises that bioavailability and bioequivalence requirements for drug products were addressed in separate proposals published in the FEDERAL REGISTER of June 20, 1975 (40 FR 26157 and 26164) and made final in the FEDERAL REGISTER of January 7, 1977 (42 FR 1624).

8. Several comments were received regarding written procedures to describe specific manufacturing and control operations. In general the comments agreed that written procedures were suitable in many instances, but were not required for every operation involved in the production and control of drug products. Specific examples were cited as requiring excessive and unnecessary written procedures. The most common example cited was § 211.67(b), which proposed, in part, that there be written procedures assigning responsibility for cleaning and maintenance and describing in detail the maintenance and cleaning schedules, the methods, equipment, and materials to be used, and the methods of disassembling and reassembling all equipment used in the manufacture, processing, packing, or holding of a drug product. The objection to the requirement of this instance appears to be in reference to "all" equipment.

The requirement for written procedures is intended to provide additinal assurance of effective communication of appropriate information from firm management to line personnel and of regular performance of a firm's established programs and procedures. It is not enough that employees "know their jobs." Key personnel may be absent without warning; personnel substitutions involving less experienced employees may be necessary; and new or revised instructions to employees must be adequately conveyed to those who need to know. These situations are not usual, but may occur frequently. The most appropriate method for reliably relating policies and procedures to those who must know them is to have them set down in writing, readily available, and presented in a manner easily understood. The Commissioner does not believe this is a burdensome requirement. The regulations do not require that a separate procedure be written for each and every individual piece of equipment. Thus, for example, similar pieces of equipment that would have the same cleaning schedule could be considered together for convenience and would be

in compliance with requirements of § 211.67(b).

9. One comment suggested that written procedures are changed frequently and the regulations make no provisions for dating the written procedures and retaining outdated written procedures. The comment pointed out that the outdated procedures may be of some value in following up problems that may have occurred during the period that the written procedures were in effect.

The Commissioner has carefully considered the merits of this suggestion and concludes that specific provisions for the dating and retention for all written procedures are not needed at this time. The regulations already contain this type of requirement for certain records such as master and batch production control records. For other procedures, it is preferable for each manufacturer to develop his scheme for dating, replacing, and retaining written procedures.

10. One comment recommended that FDA provide a complete set of correct model forms for use by individual firms in their own recordkeeping. The comment suggested that the model forms could be a part of the CGMP regulations, or FDA could furnish such information separately.

The Commissioner does not find sufficient need at this time to warrant development of such model forms. The CGMP regulations, as amended, provide sufficient detail for manufacturers to understand readily what is required for compliance with these regulations. Because of the broad nature of the regulations and the wide variety of manufacturers subject to the CGMP regulations, the Commissioner is not convinced that model forms would be so adaptable as to be useful for a majority of firms. If, however, future experience with these CGMP regulations indicates that model forms issued as guidelines would be helpful, the Commissioner will reconsider the matter.

11. A respondent suggested promulgating the regulations under section 701(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 371(e)) to give opportunities for hearings on, and judicial review of, these regulations before they take final effect.

The authority to promulgate the regulations for the enforcement of the current good manufacturing practice provisions of the act rests specifically in section 701(a) of the act. As noted in paragraph 35, Congress voted in 1962 not to require that CGMP regulations be issued under the procedures set forth in section 701(e) of the act. The Commissioner could elect to follow a procedure similar to that in section 701(e) of the act and hold a legislative type of hearing on specific aspects of this proposal under 21 CFR Part 15. After an extensive review of the numerous comments, however, he has decided that there are no particular portions of this regulation which need a further presentation of information or arguments. Any interested person may submit a petition under 21 CFR 10.30 to the Commissioner requesting such a hearing and should identify with specificity and supporting explanations the issues that might be heard. No such petition will, however, automatically delay the effective date of these regulations, as would be the situation under section 701(e) of the act; the Commissioner will grant a delay only if clearly justified.

12. In reference to the proposed requirement in § 211.184(a), that the prime manufacturer, if known, be listed, one comment recommended that the CGMP regulations require that the name and lot number of the original manufacturer of the final drug product be part of the labeling.

The Commissioner recognizes that a number of interested persons have, at various times, recommended that the labeling of drugs (whether bulk or in dosage form) bear the name of the manufacturer in addition to the distributor or repacker or relabeler. Changes such as this, however, would have such broad effect and would be likely to generate such enormous public and industry interest that the Commissioner does not believe that these final regulations are the proper place to consider them. Moreover, there are questions concerning the legality of such a requirement being adopted under section 501(a)(2)(B) of the act (21 U.S.C. 351(a)(2)(B)). Therefore, the Commissioner declines to act on this comment at this time.

II. Terminology and Language in These Regulations

13. Numerous comments were received suggesting changes in language, grammar, terminology, punctuation, sentence structure, and other editorial changes to clarify or improve upon the requirements as stated in the regulations or to eliminate redundancies or inconsistencies. Those proposals that raised significant policy questions, suggested changes in the substance of the regulation, or otherwise required, in the Commissioner's opinion, a specific response, are discussed individually below. Many of the suggested changes, however, were more editorial and stylistic and do not warrant a detailed discussion that would double the length of this preamble.

The Commissioner reviewed each of these numerous editorial and language changes to determine whether it offered an improvement in clarity or definition, eliminated an obvious error or redundancy, promoted consistency with other portions of the regulations, or otherwise identified textual problems that were not previously noted by FDA. Where the proposed alternative language or other changes suggested by them were superior to the proposal, they were adopted in substance or verbatim. Where they did not offer any improvement, the Commissioner declined to accept them.

14. One comment recommended consistent usage of the words "drug," "drug product," "phase," "step," and "stage." The comment suggested that confusion can result from using "drug" and "drug product" interchangeably because, in the technical literature, the term "drug" usually refers to the bulk drug and the term "drug product" to the finished dosage form. The comment also pointed out that the words "phase," "step," and "stage" are used interchangeably and may, in fact, describe different aspects of a production operation.

The Commissioner finds that Parts 210 and 211, as amended by this order, use "drug" and "drug product" consistently with the definitions in section 201(g) of the act and § 210.3(b)(4) of the regulations (21 CFR 210.3(b)(4)); that is, "drug products" refers to only finished dosage forms, while "drug" includes both bulk drugs and drug products. With regard to the words "phase," "step," and "stage," he finds that it is unnecessary to describe various aspects of a production operation by using different words that can have essentially the same meaning in common usage. Therefore, for clarification, the CGMP regulations are revised to use the word "phase" consistently when describing certain aspects of the manufacturing operations.

15. A number of comments concerned use of the phrase "to prevent" throughout the proposed CGMP regulations. The phrase appears in these regulations to indicate that a required procedure must be accomplished, or accomplished in a manner, to preclude a resultant deleterious effect, e.g., "containers shall be opened, sampled, and resealed in a manner to prevent contamination." In several instances, the comments objected to the phrase as being "too absolute," stating that the regulations should allow for variation from the desired objective on occasion because no firm should be expected to prevent undesirable occurrences 100 percent of the time. The phrase "designed to prevent" was suggested as an alternative. A number of comments objected to the phrase "to prevent" when used in conjunction with written procedures on the basis that written procedures in themselves do not prevent anything; they must be implemented to accomplish the desired objective. The phrase "designed to prevent" was again suggested as an alternative phrase.

The Commissioner believes that it is not acceptable to allow deviations from practices that could result in adverse effects upon the quality of the drug product, even on occasion. The Commissioner, however, does agree with the comments' contention that written procedures must be implemented to prevent anything and has adopted the phrase "designed to prevent" in the applicable portions of the final regulations.

16. Several comments objected to the use of terminology such as "adequate," "appropriate," "significant," "major" equipment and "long" periods. The objection is that these terms lack the specificity needed and will result in confusion to the manufacturer.

The Commissioner has carefully considered the use of these words and other words and phrases that imply absolute requirements in judgmental matters. Except for the changes noted in responding to the comments by specific sections, he concludes that the terminology is appropriate as set forth in the regulations. Words such as "adequate" and "appropriate" do permit reasonable, albeit variable, interpretation by reasonable people, but are necessary and desirable for regulations to have both broad applicability and flexibility. An overwhelming majority of those commenting on the proposal were greatly concerned that the regulations accommodate the wide variability of manufacturing and control systems. In fact, a number of comments recommended additional use of modifying words such as "appropriate" and "adequate" to carry a sense of flexibility in the CGMP regulations.

17. Several comments objected to the use of the word "current" in the title and text of the regulations. Other comments indicated that some of the proposed requirements, such as separation of penicillin operations in the production of veterinary drug products and the proposed statistical testing requirements, are not "current" good manufacturing practice for the industry. Another comment requested that the term "current" be defined. One comment recommended that the word "current" be deleted since it is obvious that the latest regulations to be published are current, and therefore the use of the word "current" is superfluous.

Several of these comments reflect, the Commissioner believes, a misunderstanding regarding the use of the word "current." The act itself, in section 501(a)(2)(B), specifies that a drug is deemed adulterated if the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with "current" good manufacturing practice to assure that such drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess. The Congress intended that the phrase itself have a unique meaning and that the good manufacturing practice regulations represent sound current methods, facilities, and controls for the production of drugs to assure safety, identity, strength, quality, and purity of the product. The agency determines what constitutes "current good manufacturing practice" based upon its experience with the manufacture of drugs through inspectional and compliance activities; upon knowledge gained from reviewing new drug applications, antibiotic forms, biological product and establishment licenses, and other submissions to FDA; and upon consideration of comments from interested persons received in response to proposals to amend CGMP regulations. Although the practices must be "current" in the industry, they need not be widely prevalent. Congress did not require that a majority or any other percentage of manufacturers already be following the proposed mandated practices, as long as it was a current good manufacturing practice in the industry, i.e., that it had been shown to be both feasible and valuable in assuring drug quality.

The accumulated knowledge and experience of FDA in the area of current good manufacturing practice is reflected in a body of information, which with the exception of trade secrets and information relating to pending enforcement actions has long been available to the public. This body of information, which is the basis for agency expertise with respect to current good manufacturing practice, is so voluminous that formal inclusion into the administrative record of this proceeding is not practical. Nevertheless, the Commissioner relies on this body of information in promulgating this regulation. The following list describes the information coming to FDA since active preparation of the proposal to revise the CGMP regulations began (in late 1974):

(1) FDA investigators conducted approximately 20,000 inspections of establishments in which drugs for human use are processed, and another 6,000 inspections of veterinary drug establishments. After each inspection, an FDA investigator filed an establishment inspection report with the agency. With rare exceptions (for cases subject to active law enforcement investigation), these reports are promptly available as public information under FDA's Freedom of Information regulations (21 CFR Part 20).

(2) FDA received approximately 1,000 full new drug applications (including original submissions, resubmissions, and amendments), 1,500 abbreviated new drug applications, and 6,900 new animal drug applications. Each application contains information pertaining to the manufacturing processes to be used in producing the drug subject to the application. In addition, about 10,000 supplements to approved applications, many relating to manufacturing processes, were submitted. FDA must review and approve these processes before an application may be approved. The contents of approved new drug applications, except those portions that constitute trade secrets, are available for public inspection. (21 CFR 314.14, 431.71, 514.11, and 601.51.)

(3) FDA monitored more than 1,200 recalls of drugs for human use and 275 recalls of veterinary products. In each recall resulting from a product defect, FDA investigates to determine the manufacturing control problems that led to the defect. These investigations, generally embodied in establishment inspection reports, are also publicly available upon completion of regulatory activities.

(4) FDA brought over 500 legal proceedings—criminal proceedings, seizures, and injunctions—involving drugs for human use and veterinary products. Again, in those proceedings arising from product defects, a full investigation has been conducted to support the agency's case. In addition to the establishment inspection reports, testimony, documented evidence, and court papers are publicly available.

Furthermore, FDA representatives have participated in numerous activities—meetings, seminars, and workshops (regarding CGMP's, industry practices, and agency policies)—with organizations such as Parenteral Drug Association, the Proprietary Association, the National Association of Pharmaceutical Manufacturers, Pharmaceutical Manufacturers Association, the Packaging Institute, University of Wisconsin Industrial Pharmacy Management Conference, and the American Society for Quality Control. These activities further contribute to the knowledge and experience of FDA. Many of the organizations sponsoring these activities publish publicly available proceedings of these meetings, e.g., *Journal of the Parenteral Drug Association* and *Proprietary Association Manufacturing Controls Seminar Presentations.*

For additional information summarizing FDA's activities for the past several years, see 1975–1977 Annual Reports and fiscal year 1979 Justification of Appropriation Estimates for Committee on Appropriations. (Copies

have been placed on file with the office of the Hearing Clerk, FDA.)

18. Several comments asserted that CGMP regulations must reflect the "current" practices of manufacturers of a particular type of drugs. Others objected to the absence of findings specifically supporting the conclusion that a particular practice was a "current" practice of the manufacturers of a particular type of drug product. Among the drug products cited as the appropriate measure for current good manufacturing practice were veterinary drugs, medical gases, radio- pharmaceuticals, and cosmetic-type drug products.

The Commissioner recognizes that different types of drug products may require specialized manufacturing and control procedures or may not be appropriate to the application of certain procedures that are otherwise generally applicable to drug products. For this reason, he has announced his intention to issue specialized current good manufacturing practice regulations for particular types of drug products and, in fact, has already issued one such proposal regarding large volume parenteral drug products. The regulations set forth in Part 211 (21 CFR Part 211) are designed to be applicable to all drug products in finished dosage form. They are based on practices widely used throughout the industry for manufacture of many finished drug products. The Commissioner rejects the idea that FDA must establish that each CGMP requirement is a current practice of the manufacturers in each subset of drug products covered by the general requirements of Part 211. As noted elsewhere in this preamble, the commissioner has evaluated whether this requirement is appropriate for particular types of drug products in response to specific comments. Where he has found it to be inappropriate, he has exempted the products from the requirement; otherwise the commissioner has concluded that all manufacturers of finished drug products should be subject to the requirements of Part 211. The Commissioner believes this is the only feasible way to approach such general current good manufacturing practice regulations. There is no consensus on the various subgroups of finished drug products, and therefore a requirement that the currency of practice must be documented for each subgroup would ultimately amount to establishing that it was a current practice by each manufacturer of each drug product, a burden which would be impossible to establish and unnecessary for purposes of regulation. Therefore, the Commissioner rejects these comments.

III. Amendments Regarding Placement of Expiration Date on Drug Product Labels

19. A substantial number of comments objected to the proposed requirement in § 201.17 that the expiration date appear on the shipping carton. The majority objected on the grounds that it is common practice for shipping containers to contain different drug products or similar drug products with different expiration dates. Some persons recommended that the expiration date be required on the shipping carton only when the carton is for one drug product.

The Commissioner recognizes that there are valid reasons for comingling various drug products, or different lots of the same drug product, within a single shipping carton. In such instances it may not always be practicable for each different expiration date to appear on the shipping carton. Because of significant differences in the use and labeling of shipping cartons, the Commissioner concludes that a requirement for the expiration date to appear on the shipping carton when such shipping carton is not the immediate container should not be a part of the regulations at this time, and this requirement is deleted from § 201.17. Manufacturers are encouraged, however, to provide appropriate information to the extent possible on all shipping cartons to facilitate handling, reduce the possibility of mixups, and allow easy identification of lots that are being recalled or withdrawn from the marketplace.

20. Several comments were received regarding expiration dating of shipping cartons containing radio- pharmaceuticals. Generally, the comments were that such drugs usually have several separate component parts each with a different expiration date. One comment requested an exemption from the entire section, while another comment asked for an exemption for the shipping carton.

The Commissioner believes that § 201.17, as revised, will accommodate the special problems encountered in the handling of radiopharmaceuticals.

21. Several comments suggested that the heading of this section be revised by changing the title word from "drugs" to "drug product" to conform to the drug product definition in § 210.3(b)(4).

The Commissioner finds that the word "drugs" in the heading of § 201.17 is more consistent with the terminology used in Part 201. The term "drug product," as defined in § 210.3(b)(4), is intended specifically for use in Part 211 to convey a meaning more limited than the general term "drug" as defined in section 201(g) of the act. However, to clarify that § 201.17 applies to drug products under Parts 210 and 211, the final regulation in § 201.17 is revised to refer to both drugs and drug products.

22. A number of comments recommended that the expiration date not be required on outer retail package labeling, such as display cartons, if the expiration date appearing on the immediate container is visible.

The Commissioner agrees that it was his intention to require that the expiration date be visible under usual and customary conditions of packaging. He notes that section 201(k) of the act provides for label information that is easily legible through the outside container or wrapper. Section 201.17 is revised to allow such alternative placement of the expiration date.

23. One comment said the proposed section does not clearly cover a situation where the producer does not package the material in a retail package, but markets drug products in bulk containers.

Although the Commissioner believes that the situation described is covered by the proposed regulations, the final regulation as rewritten clearly specifies that when the expiration date of a drug, including drug products, is required, it shall appear on the immediate container. There is no exemption for drug products in bulk containers.

24. One comment recommended that § 201.17 specifically exclude "wrappers" for individual tablets, lozenges, and suppositories from the requirement of bearing an expiration date.

The Commissioner finds that it is generally understood that protective wrappers for individual dosage forms that are further packaged in immediate containers are not required to bear an expiration date. Because only one comment about protective wrappers was received requesting a statement in the regulations and no information was submitted that the issue raised has actually been a problem, the Commissioner concludes that further clarification of this section is not now warranted.

25. Several comments asked about the acceptability of placing the expiration date on the crimp of the drug product tube.

Because of the wide variety of available methods and techniques of applying and presenting expiration dating information on the immediate container, the Commissioner has not attempted to specifically evaluate and list individual methods. In general, he finds that the expiration date should be readily seen under usual and customary circumstances. The tube crimp has been used for placing the lot or control number (as provided for under § 201.100(b)(6)) and for placing the expiration date for some products. No known problems have been associated with such information appearing on

the crimp of the dispensing tube and, therefore, this method is an acceptable way to comply with § 201.17.

26. Several comments objected to the provisions in § 201.17 that when single-dose containers are packed in individual cartons, the expiration date may properly appear on the carton only. Several respondents noted that ampules are sometimes removed from the outer carton, particularly in hospitals, and that valuable information that is not a part of the immediate container labeling is lost.

The provision in this section regarding single-dose containers has been in effect for a number of years and was based on information that such an allowance was necessary for single-dose containers, primarily glass ampules, because of technical problems in labeling glass ampules on a batch-by-batch basis. Some manufacturers are now placing expiration dates on single-dose containers; however, no information has been presented that expiration dating for all single-dose containers, particularly glass ampules, is feasible. Although the Commissioner recommends this activity, it was not his intent to propose revocation of the exemptions for single-dose containers as part of this revision of FDA regulations. Based on the few comments received which recommended additional revisions in this section, the Commissioner will not revoke these exemptions at this time, but will consider the recommendations for revisions for a future proposal.

27. Several comments recommended that for drugs which are also cosmetics (see also paragraph 42(h)) expiration dates should only be placed on the shipping carton and outer retail package because such products are typically purchased by the user with the outer retail package intact and the product is consumed in a relatively short period of time.

The Commissioner advises that under the interim provisions of § 211.137(f), most of these types of products will be exempted from the expiration dating requirements. But the so-called "drug-cosmetic" type of products are not free from stability problems; therefore, unless such products are stable for at least 3 years, expiration dating is required (see also paragraph 353 of this preamble).

IV. Amendments Regarding Drug Listing and Establishment Registration Requirements for Drug Product Salvaging Operations

28. Several comments suggested that the word "human" be inserted between the words "licensed" and "biologicals" in § 207.3(b) because veterinary biologicals are regulated by the U.S. Department of Agriculture.

The Commissioner agrees with these comments and is amending the paragraph accordingly.

29. One comment recommended that the definition of "establishment" under § 207.3(b) be broadened to include additional categories such as bulk sales by practitioners, antique shops, and dealers and trustees handling estate sales and/or bankruptcies.

The Commissioner agrees that these are all examples of establishments that could engage in drug-salvaging operations, but believes that the proposed definition of "establishment" is preferred in order to provide coverage for any type of establishment that engages in drug product salvaging operations, including those identified in the comment.

30. Two comments suggested deletion of the word "may" in the phrase "may have been subjected to" improper storage conditions in the proposed § 207.3(k) because the statement is too general and the requirement should only apply when the drug product has actually been exposed to adverse conditions.

The Commissioner rejects this suggestion because it may not be possible in every instance to establish clearly the exact nature of the adverse circumstance to which a drug product has been exposed. Therefore, in some instances, the salvager may only have sketchy information about improper storage conditions, such as unusual temperatures, and must assume that such conditions may have occurred in order to handle the salvaging operations properly.

31. Three comments concerned the proposed exemption of drug product salvagers from drug listing in § 207.20. Two of the comments recommended that drug product lists be submitted prior to salvaging and one respondent recommended that a drug product list need not be submitted, but should be maintained by the salvager.

The Commissioner agrees that an inventory of drugs subjected to salvaging operations should be maintained, but does not agree that salvagers should submit a drug list under Part 207 (21 CFR Part 207). To clarify that an inventory of drugs involved in salvaging operations shall be maintained, provisions are added in § 211.208 for maintenance of records for drug products subjected to salvaging operations.

32. One comment considered the registration requirement for a drug salvaging firm to be a waste of taxpayers' money and recommended that the recycling of any and all drugs and pharmaceuticals be prohibited.

The Commissioner disagrees with this opinion. He does not agree that drug product salvaging should be prohibited where the integrity of the drug product is not compromised. Otherwise costs to consumers might be increased. Individual firms are in a better position to determine the financial feasibility of a salvaging operation. The costs of registration, both to the Government (and the taxpayer) and to the registrant, are quite insignificant and probably less than the added costs that would result from the needless destruction of salvageable drug products.

V. Legal Status of CGMP Regulations

33. Several comments requested deletion of the word "drugs" in the title and insertion of the words "drug products" in order to be consistent with the title of Part 211 and the definition of § 210.3(b)(4) and § 210.1(a).

Part 210 applies to all parts between Parts 211 and 229. Part 211 deals with finished dosage forms, but other parts may not. Therefore, the Commissioner finds that the more general term "drugs" applies better to the various types of drugs that are likely to be covered in Parts 211 to 229.

34. A number of comments objected, on diverse grounds, to use of the word "minimum" to describe the requirements in these regulations. Several respondents believed that current good manufacturing practice cannot be considered in terms of a "minimum" because that implies that firms adhering to the regulations are then merely at a threshold level of compliance. Other respondents suggested that "minimum" means that normal practices represent a higher standard and that there is an implication that the standards of these regulations fall below an acceptable level. Some comments recommended that "minimum" not be used because no such reference to CGMP regulations is in the act.

The Commissioner does not agree with these comments. The legislative history of the Drug Amendments of 1962 shows that section 501(a)(2)(B) of the act was included to raise the standards of drugs manufacturing by all manufacturers to the level of the current good manufacturing practice in the industry. Congress was quite concerned about the uneven and sometimes unacceptable quality of drug products from some portions of the pharmaceutical industry. The purpose of section 501(a)(2)(B) of the act is to provide assurance that drug product quality would not fall below that which was feasible and available under contemporary technology. There is no implication that the standards represented by these regulations are less than acceptable or below the industry's norm. On the other hand, there is no prohibition in the regulations against the manufacturing of drug products using better, more efficient, and innovative methods. In fact, the

Commissioner encourages use of such methods because it benefits the consumer. Although the word "minimum" does not appear in section 501(a)(2)(B) of the act, its use is necessary in the CGMP regulations because of their binding legal nature (discussed in paragraph 35); that is, failure to meet the minimum standards of the regulation results in the product's being adulterated.

BINDING DRUG CGMP REGULATIONS

35. Several comments argued that § 210.1 should be deleted because it is based on the erroneous proposition that CGMP regulations can be substantive. The comments urged that regulations issued under section 501(a)(2)(B) of the act are only interpretive. In support of their argument, many referred to the legislative history of the Drug Amendments of 1962. One comment stated the following:

Section 501(a)(2)(B) was enacted as part of the Drug Amendments of 1962, and, as reported by House Committee, those amendments would have included a provision empowering the FDA to issue GMP regulations under it formal section 701(e) rulemaking authority. (H.R. 11581, 87th Congress, Second Session.) The House Committee Report explained: "The promulgation of these regulations would be subject to opportunity for hearing and judicial review. Thus, legal action could be brought against firms failing to abide by these standards and against the products they ship." (H.R. Rep. No. 2464, 87th Congress, Second Session, 2(1962).) The present form of section 501(a)(2)(B) was first enacted by the Senate. The Senate Committee Report made clear that the provision was intended to authorize the FDA to issue "interpretative" regulations that would constitute only prima facie evidence of adulteration. (S. Rep. 1744, 87th Congress, Second Session, 9(1962).) In floor action on September 27, 1962, the House amended H.R. 11581 to be consistent with the Senate bill. (108 Congressional Record 19916 (daily edition 1962).)

Most of those relying on the legislative history argument quoted from the same Senate Committee Report.

Other comments objecting to FDA's authority to issue binding CGMP regulations asserted that the four judicial decisions cited in the preamble to the February 13, 1976, proposal in fact did not support that authority. One comment reviewed the history of all four proceedings and concluded:

All of the cases cited by the Commissioner * * * recognize that the court cannot reach a conclusion contrary to Congressional intent. In those cases, there was no clear Congressional intent and the courts allowed the FDA to issue substantive regulations under section 701(a) of the Act. The legislative history with respect to the proposed CGMP regulations is crystal clear and does not permit the Commissioner to issue substantive regulations.

Because of the fervor reflected by these objections and because the Commissioner foresees identical objections being made to proposals to issue binding CGMP regulations for specific classes of drug products in the future, the Commissioner has decided that a lengthy exposition of the basis for his concluding that FDA has legal authority to promulgate such regulations is warranted. The Commissioner intends that this statement will be definitive, and he does not contemplate reconsidering the issue of FDA's legal authority to issue substantive CGMP regulations in the future unless new materials, not discussed below, are brought to his attention. The question of whether a particular regulation should be issued as binding or interpretive, of course, may always be raised, and comments on the wisdom of making these CGMP regulations binding are discussed in paragraph 36 below in this preamble.

With regard to the legislative history of the Drug Amendments of 1962, the Commissioner finds that none of the comments provided a complete or accurate picture of the enactment of the current section 501(a)(2)(B) of the act. Because of the emphasis placed by the persons objecting to "substantive" CGMP regulations on Congressional intent, the Commissioner believes a detailed review is necessary.

On July 19, 1962, the Senate Judiciary Committee reported out S. 1552, the Senate version of what ultimately became the Drug Amendments of 1962. Section 5 of the July 19 bill would have amended section 501(a)(2) of the act to read as follows:

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess. The Secretary is authorized to issue interpretative regulations, upon notice and in accordance with the procedures set forth in section 4 of the Administrative Procedure Act (5 U.S.C. 1003), which shall, in any proceeding involving this paragraph, be prima facie evidence of what constitutes current good manufacturing practice.

The accompanying bill report (S. Rep. No. 1744, 87th Cong., 2d Sess. (July 19, 1962)), described this section at page 9, emphasizing that the "Secretary would be authorized to issue interpretative regulations as to what constitutes current good manufacturing practice, and these regulations would be prima facie evidence in any proceeding under this section of the Food, Drug, and Cosmetic Act."

On August 3, 1962, President Kennedy submitted a series of amendments to the Senate Judiciary Committee. In response to this and to the public controversy then erupting over thalidomide, the Committee reconsidered S. 1552 and, on August 21, 1962, reported out a revised version of the bill. One change was to reword section 5 of the bill so that section 501(a)(2) would be amended to read as follows:

(2)(A) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The Judiciary Committee issued a second report to explain its proposed changes in S. 1552 (S. Rep. No. 1744, Pt. 2, 87th Cong., 2d Sess. (Aug. 21, 1962)). On pages 3 and 4, it discussed the revision of section 5 as follows:

The President, in the recommendations submitted for the consideration of the committee with his letter of August 3, 1962, proposed a revised version which included the following principal amendments to the reported bill:

(1) It proposed to replace the provisions on regulations with prima facie evidentiary effect with a provision that the adequacy of the quality controls be determined "in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice" after formal rulemaking procedures, i.e., after affording an opportunity for hearing, and for judicial review on the basis of the hearing record, with respect to such regulations.

* * * * *

The explanation accompanying the recommendations of the President expressed concern lest the language as to interpretative regulations with prima facie evidentiary effect invite endless de novo litigation on the question of what constitutes a good manufacturing practice each time there is enforcement action under the new quality control provisions. The committee acceded to the President's request for elimination of the "prima facie" regulatory authority in the bill. It felt, however, on balance, that there was no need for inserting provisions for regulations through formal rulemaking on the subject of what is good manufacturing practice. Section 701(a) (21 U.S.C. 371(a)) now vests in the Secretary "authority to promulgate regulations for the efficient enforcement of this Act." This permits the Department to issue such regulations as it desires and their scope and effect will be the same as that of other regulations issued under such general authority. Numerous regulations have been issued under section

701(a) and have been the subject of consideration and application in the courts in actions arising under the various provisions of the act not now subject to formal rulemaking procedures.

During the floor debate on S. 1552 on August 23, Senator Eastland, Chairman of the Judiciary Committee, elaborated on the meaning of section 501(a)(2) as it would be amended by the bill:

Section 5, as it would read under the August 20 amendments, is designed to assure that drugs are manufactured according to good manufacturing practice. It would deem a drug to be adulterated and thus subject to seizure if made under facilities, methods, or controls that are inadequate to assure that the drug meets the specifications of a quality product. Adulteration could also be found if such facilities, methods, or controls were not operated or administered in conformity with good manufacturing practice.

Since the competitive position of responsible manufacturers depends in large part on the confidence of the medical profession and the public, it will be in their own interest to maintain high standards of current good manufacturing practice which will provide a readily determinable basis for enforcement proceedings against any substandard operator. The Secretary could use his general rulemaking authority under section 701(a) of the act to announce what he, in the administration of the act, considers to be good manufacturing practice insofar as methods, facilities, controls, and their operation and administration are concerned. As in the case of other regulations, the court in the final analysis will pass upon the scope and effect of such regulations. (108 Cong. Rec. 16303-4 (Aug. 23, 1962).)

Senator Kefauver concurred in this change, stating, "This provision has been strengthened considerably in comparison to the bill which was reported in July." (Id., at 16306-7).

The Commissioner thus concludes that when it unanimously approved S. 1552 on August 23, 1962, the Senate obviously believed that the problem identified by the President—"endless de novo litigation * * * each time there is enforcement action"—had been resolved. The Senate must, therefore, have intended that regulations issued under section 501(a)(2)(B) of the act be more than merely prima facie evidence of what constitutes current good manufacturing practice, i.e., that they be given at least the same force as any other regulation issued under section 701(a) of the act. He also finds that the statement relied upon by most comments as proof that only interpretive regulations could be issued appeared in the first Senate Report and was explicitly reversed in the second Senate Report.

One month later, the House Interstate and Foreign Commerce Committee reported out H.R. 11581, the House bill that preceded the Drug Amendments of 1962. (H.R. Rep. No. 2464, 87th Cong., 2d Sess. (1962)). Section 101(a) of this bill proposed to amend section 501(a)(2) of the act to read as follows:

(2)(A) if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice (as determined in accordance with regulations promulgated by the Secretary) to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

In addition, paragraph (b) of section 101 would have amended section 701(e) of the act to provide that regulations under section 501(a) would be issued by formal rulemaking procedures (rather than the informal procedures under section 701(a) of the act).

The Committee Report accompanying H.R. 11581 explained this provision as follows (H. Rep. 2464, 87th Cong., 2d Sess. 2 (Sept. 22, 1962)):

Section 101 of the reported bill would amend section 501(a)(1) [sic] of the Federal Food, Drug, and Cosmetic Act to deem a drug to be adulterated if the methods, facilities, or controls used in its manufacture, processing, packaging, or holding fail to conform to, or are not operated or administered in conformity with, good manufacturing practices as determined in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare which are designed to assure that the drug is safe and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess * * *

The promulgation of these regulations would be subject to opportunity for hearing and judicial review. Thus, legal action could be brought against firms failing to abide by these standards and against the products they ship.

The House of Representatives debated H.R. 11581 on September 27, 1962. Congressman Schenck offered several amendments that day, one of which would delete the parenthetical element in section 101(a), and all of section 101(b), from the bill. He explained this amendment as follows:

My amendment to section 101 of the bill, which was approved by the committee, provides simply that the drug will deem [sic: be deemed] to be adulterated and subject to seizure if the methods, facilities, or controls used in the manufacture of the drug do not conform with current good manufacturing practice, as determined in accordance with regulations promulgated by the Secretary.

The purpose of this provision is to enable the Secretary to require all companies producing drugs to observe the high standards that are now followed by the better manufacturers. It is intended that the Secretary's regulations will define minimum standards of good manufacturing practice, rather than setting forth an exclusive method by which some particular drug product may be made. Manufacturers whose methods, facilities, and controls exceed the minimum standards will not be required to lower their own standards, so long as they can show that their own practices meet or exceed these minimum requirements.

The principal purpose of the provision is to assure that the same high manufacturing standards are followed in making so-called old drugs that the law now requires in the making of so-called new drugs. Before any manufacturer is permitted to make a new drug he must file complete details of his manufacturing process with the Food and Drug Administration. It is not intended that the regulations issued under section 101 will apply to the manufacturer of new drugs insofar as the methods, facilities, or controls used in making these new drugs but that the Food and Drug Administration will require that such drugs meet the requirement of this act as to safety, and has the identity and meets the quality and purity characteristics which it purports or is represented to possess.

The committee adopted an amendment which would make the formal rulemaking procedures of section 701(e) of the Federal Food, Drug, and Cosmetic Act applicable to regulations referred to which may be made pursuant to the above amendment.

I am opposed to the amendment in section 101(b) of the bill which would require the Secretary to hold a formal hearing under section 701(e) of the Federal Food, Drug, and Cosmetic Act in order to issue regulations as to what constitutes 'current good manufacturing practice.' I favor the approach adopted by the Senate under which this determination is made pursuant to section 701(a) of the act. This procedure permits the Secretary to issue such regulations as he desires and their scope and effect will be the same as that of other regulations issued under such general authority. This procedure is more flexible. Numerous regulations have been issued under this section and they have been the subject of consideration and application in the courts in actions arising under the various provisions of the act not now subject to formal rulemaking procedures. (108 Cong. Rec. 19895-6 (Sept. 27, 1962).)

The Schenck amendment was concurred in by Congressman Harris, Chairman of the House Commerce Committee, who observed that the amendment "is taken, in part, from the Senate bill, S. 1552 * * * The gentleman from Ohio [Mr. Schenck] has advised me of the need not to tie this provision in with section 701(e) * * *" 108 Cong. Rec. 19916 (Sept. 27, 1962). The amendment was agreed to and, as approved by the House of Representatives, the legislation would amend section 501(a)(2) to read:

(2)(A) if it has been prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the require-

ments of this act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

The Commissioner finds from this history that the House of Representatives believed that CGMP regulations would have the same legal status as other FDA regulations, and moved to revise language to conform to S. 1552, as passed, solely to eliminate the requirement that CGMP regulations be issued pursuant to the formal rulemaking procedures of section 701(e) of the act.

Because there was no difference between the House and Senate bills insofar as the amendment of section 501(a)(2) of the act was concerned, it was not a subject of the Conference Report (H. Rep. No. 2526, 87th Cong. 2d Sess. (Oct. 3, 1962)), nor was it modified or debated further by either the Senate or the House when each voted to approve the Drug Amendments of 1962 (on October 3 and 4, 1962, respectively).

Based on this complete review of the legislative history of section 501(a)(2)(B) of the act, the Commissioner concludes that there is no support for the proposition that Congress intended that CGMP regulations should be merely interpretive. At the least, Congress wanted CGMP regulations to have the same force and effect as other regulations issued under section 701(a) of the act. (See the second Senate Report and Rep. Schenck's description of his amendment, above). To the extent that a stronger Congressional mandate can be gleaned from the various reports, amendments, and debates, it appears that binding standards were to be issued by FDA and issued through the less cumbersome notice-and-comment rule making procedures of section 701(a) of the act rather than the more complex section 701(e) mechanism. Therefore, the Commissioner rejects the argument that § 210.1 exceeds the authority conferred by Congress under sections 501(a)(2)(B) and 701(a) of the act.

With respect to judicial interpretations of FDA's authority to issue substantive rules, the Commissioner believes that the cases cited in the February 13, 1976 preamble and decisions handed down since February 13, 1976 are directly relevant to, and further support, his conclusion that CGMP regulations can be issued as binding standards.

In 1973, the Supreme Court reviewed the legality of two interrelated FDA regulations. One, now codified in 21 CFR 314.111(a)(5), set forth in detail the scientific principles that the Commissioner believed are part of the requirement in section 505(d) of the act that the effectiveness of a drug be demonstrated by "substantial evidence consisting of adequate and well-controlled studies." The second regulation, now codified in 21 CFR 314.200, contained standards for FDA to determine whether a request for a hearing on the denial or withdrawal of approval of a new drug application (NDA) presented a genuine and substantial issue of fact. At stake in the case of *Weinberger* v. *Hynson, Westcott and Dunning, Inc.*, 412 U.S. 609 (1973), was whether an applicant was entitled to a full evidentiary hearing on the approvability of its product, and at such a hearing could offer whatever evidence it felt met the statutory standards of effectiveness, or whether FDA could summarily deny or withdraw approval of the NDA because the agency found that the applicant's evidence did not meet the standards in the regulations for evidence of effectiveness. Manufacturers contended that FDA's regulations could not serve as the basis for denying them a full evidentiary hearing under section 505 of the act. The agency believed that the regulations were a reasonable method of screening out unnecessary hearings and thereby managing an otherwise overwhelming workload. The Supreme Court concluded that both of the regulations were within the authority of the Commissioner under section 701(a) of the act and therefore FDA could act on NDA's without a full hearing where evidence failed to satisfy the FDA regulations. It said (id. at 622):

> The standard of 'well-controlled investigations' particularized by the Regulations is a protective measure designed to ferret out those drugs for which there is no affirmative, reliable evidence of effectiveness. The drug manufacturers have full and precise notice of the evidence they must present to sustain their NDA's, and under these circumstances we find the FDA hearing regulations unexceptionable on any statutory or constitutional ground.

The Supreme Court, in this and related cases, discussed FDA's authority to determine whether a drug was a "new drug" under section 201(p) of the act (and thus subject to the requirements of section 505 of the act). It described favorably the review of over-the-counter (OTC) drugs under the procedures set forth in 21 CFR 330.10, by which OTC drugs are being classified as "new" or "generally recognized as safe and effective and not misbranded," the latter not subject to the new drug provisions of the act. These procedures were also promulgated under the authority of section 701(a) of the act. The Court stated, in *Weinberger* v. *Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973) that:

> We think that it is implicit in the regulatory scheme, not spelled out in haec verba, that FDA has jurisdiction to decide with administrative finality, subject to the types of judicial review provided, the 'new drug' status of individual drugs or classes of drugs. The deluge of litigation that would follow if 'me-too' drugs and OTC drugs had to receive de novo hearings in the courts would inure to the interests of manufacturers and merchants in drugs, but not to the interests of the public that Congress was anxious to protect by the 1962 amendments, as well as OTC drugs and drugs covered by the 1972 [Drug Listing] Act. We are told that FDA is incapable of handling a caseload of more than perhaps 10 or 15 de novo judicial proceedings in a year. Clearly, if FDA were required to litigate, on a case-by-case basis, the 'new drug' status of each drug now marketed, the regulatory scheme of the act would be severely undermined, if not totally destroyed. Moreover, a case-by-case approach is inherently unfair because it requires compliance by one manufacturer while his competitors marketing similar drugs remain free to violate the Act * * *.

In a third case decided at the same time, *Ciba Corp.* v. *Weinberger*, 412 U.S. 640 (1973), the Court said (id. at 643–4) that "the definition of new drug as used in section 201(p)(1) involves a determination of technical and scientific questions by experts. The agency is therefore appropriately the arm of Government to make the threshold determination of the issue of coverage * * *."

The Commissioner notes that even prior to these rulings, most major manufacturers of OTC drugs had recognized the reasonableness as well as legal propriety of the OTC review as a mechanism within the authority of section 701(a) of the act to classify drugs as "new" or "not new." Indeed, for over 5 years now, these firms have been participating in this review, and the Commissioner expresses his gratitude for this cooperation.

Subsequent to these rulings by the highest Federal court, another case arose over the issue of whether FDA could promulgate regulations under section 701(a) of the act that represented binding rules relating to prescription drugs under section 503(b) of the act. The specific issue was whether FDA could, by regulation, declare products containing more than certain amounts of vitamin A or D to be prescription drugs. The opponents of the regulation, in an interesting parallel to the comments on the CGMP regulations, argued that only regulations issuable under section 701(e) of the act procedures could be binding and that the legislative history of section 503(b) of the act demonstrates that FDA could issue only interpretive regulations. The United States Court of Appeals for the Second Circuit rejected these contentions in *National Nutritional Foods Ass'n.* v. *Weinberger*, 512 F.2d 688 (1975). It stated:

> We have come to recognize that, if the administrative process is to be practicably effective, specific regulations promulgated pursuant to general statutory delegation of authority must be treated as authoritative, whether labeled "substantive" or "interpre-

tive," especially in areas where the agency possesses expertise not shared by the courts. In the event its views are unlikely to be distributed by the court in an enforcement proceeding * * *. Whatever doubts might have been entertained regarding the FDA's power under § 701(a) to promulgate binding regulations were dispelled by the Supreme Court's recent decisions in *Weinberger* v. *Hynson, Westcott, & Dunning* * * * and its companion cases * * *. (id. at 696).

* * * * *

Surely an agency which possess the power to determine administratively what products are "new drugs" has the authority to decide what products are "prescription drugs". (id. at 699).

The decisions in the *National Nutritional Foods, Hynson, Bentex,* and *Ciba* were cited by the Commissioner because he believes that they conclusively rule that regulations issued under section 701(a) of the act are binding and that the justifications for issuing substantive regulations in other areas are directly applicable to CGMP regulations. Similar to the Court's observations in *Hynson* quoted above, the statutory standard of "current good manufacturing regulations" can and should be particularized as a protective measure to identify those manufacturing practices which are at a minimum necessary to assure drug quality. The drug manufacturers have full and precise notice of the CGMP requirements they must fulfill to sustain the acceptability of their products under section 501(a)(2)(B) of the act, as the Commissioner noted in the February 13, 1976, preamble. Substantive regulations also provide greater certainty about the agency's expectations because, in promulgating such regulations, the agency must carefully distinguish standards it seriously intends to enforce from those it finds desirable but not essential. The Commissioner also stated in the 1976 proposal that binding CGMP regulations would assist courts and expedite enforcement proceeding under the act.

As with "new drug" determinations discussed in *Bentex,* if each CGMP requirement has to receive a de novo hearing in each and every enforcement proceeding, the burden of litigation that would result would not be in the public interest, nor would it be equitable to competing manufacturers who where not involved in such litigation. President Kennedy and the second Senate Report made the same arguments in deleting the reference to interpretive regulations from S. 1552. The agency has avoided this problem over the last several years because agency priorities have been concentrated in areas other than drug CGMP enforcement; it is not anticipated that this allocation of resources will continue indefinitely and, with the issuance of these regulations, more regulatory proceedings are probable.

In *Ciba,* the Court noted the technical and scientific expertise appropriate for at least the threshold determination of "new drug" status. The Commissioner believes that determination of what is the "current good manufacturing practice" in the drug industry also requires technical and scientific expertise, as well as a unique ability to observe the entire industry. These CGMP regulations were developed with the participation of pharmaceutical chemists employed by FDA, individuals qualified by formal training as well as by valuable experience in reviewing the good (and bad) current (and past) production and control techniques set forth in original NDA's and abbreviated NDA's, supplemental applications, antibiotic certification forms, biological establishment and product licenses, new animal drug applications, and proposed and final compendial standards. In addition, FDA investigators who conduct and/or review inspections of manufacturers under the act also participated in preparing this document. Although, as one comment noted, FDA does not manufacture drugs, it does not follow that FDA cannot determine current good manufacturing practice for drugs. On the contrary, FDA may be uniquely able to do so, because it and it alone has had access to the facilities and records of every manufacturer of pharmaceuticals in this country. Given the fact that many production and control processes are considered by individual firms to be trade secrets, it is unlikely that competitors or independent private third parties such as compendial authorities have the same ability as FDA to discover what nonpublic practices other than their own are current and which of these are good.

Subsequent to the February 1976 proposal, other courts have considered and affirmed FDA's authority to promulgate binding of substantive regulations pursuant to section 701(a) of the act. See, e.g., *Cosmetic, Toiletry and Fragrance Association* v. *Schmidt,* 409 F. Supp. 57 (D.D.C., Feb. 3, 1966), appeal docketed No. 76-1242 (D.C. Cir., Feb. 5, 1976) (regulation requiring warning labels on aerosolized products, issued under sections 201(n), 602(a), and 701(a) of the act, upheld; *American Frozen Food Institute* v. *Mathews,* 413 F. Supp. 548 (D.D.C. March 30, 1976), aff'd sub nom. *American Frozen Food Institute* v. *Califano,* 555 F.2d 1059 (D.C. Cir. May 12, 1977) (regulations establishing common and usual names for nonstandardized foods, issued under sections 403(i) and 701(a) of the act, upheld); *National Confectioners Ass'n.* v. *Mathews,* CCH Food, Drug & Cos. L. Rep. ¶ 38,062 (D.D.C. April 14, 1976), aff'd sub nom. *National Confectioners Ass'n* v. *Califano,* Docket No. 76-1617 (D.C. Cir. Jan. 20, 1978) (CGMP regulations for cocoa products and confectionery relating to lot coding on finished product packages and shipping containers and to distribution records of lots, issued under sections 502(a)(4) and 701(a) of the act, upheld); *Federation of Homemakers* v. *Schmidt,* 385 F. Supp. 362 (D.D.C. 1974), aff'd 539 F.2d 740 (D.C. Cir. June 10, 1976) (regulation establishing requirements for "imitation" foods, issued under sections 403(c) and 701(a) of the act, upheld); *Almay, Inc.* v. *Weinberger,* 417 F. Supp. 758 (D.D.C. June 30, 1976), rev'd on the grounds, No. 76-1718 (D.C. Cir. Dec. 21, 1977) authority to issue regulations regarding labeling and supporting evidence of cosmetics claiming to be "hypoallergenic," under sections 301(b), 602 (a) and (b) and 701(a) of the act upheld); *United States* v. *Nova Scotia Food Prod. Corp.,* 417 F. Supp. 1364 (E.D.N.Y., Aug. 17, 1976), rev'd on the grounds, No. 76-6169 (2d Cir. Dec. 15, 1977) (CGMP regulations regarding brining and heating of fish in the production of smoked fish may be promulgated under sections 402(a)(4) and 701(a) of the act). The Commissioner notes that two of the cases dealt specifically with the validity of CGMP regulations issued under the statutory standards relating to adulterated foods, which do not explicitly refer to "current good manufacturing practice." It would indeed be anomalous that those regulations could be issued as legally binding if regulations amplifying section 501(a)(2)(B) could not be.

The Commissioner interprets much of the concern over FDA's authority to issue binding regulations as reflecting a belief that the CGMP regulations can be arbitrary, need not be based upon actual current practice, and may exceed what is necessarily "good" for drug quality. There also seems to be a belief that binding regulations cannot be changed and are beyond review by the courts. These perceptions are in error.

The Administrative Procedure Act clearly provides that regulations which are arbitrary or capricious may be overturned by a reviewing court. 5 U.S.C. 706. The legislative history of section 501(a)(2)(B) of the act and cases involving enforcement of CGMP regulations, e.g., *United States* v. *An Article of Drug* * * * *"White Quadrisect",* 484 F.2d 748 (7th Cir. 1973)) established that the regulations must be based on current industry practice, although not necessarily on the predominant practice in the industry. The agency is directed to consider the current "good" practices. In determining current practice, the agency has

relied upon the knowledge and expertise of FDA staff developed from the review of NDA's and ANDA's, antibiotic certification forms, biological licenses, and compendial standards submitted to the agency, and from establishment inspections made during the last half decade. A "good" practice was included in these regulations only if it is feasible for manufacturers to implement the practice, if the practice contributes to assuring the safety, quality, and purity of the drug product, and if the value of the contribution or added assurance exceeds the cost, in terms of dollars and/or other burdens, of implementing or continuing the practice. The Commissioner does not believe it is legally required that, in addition to reliance upon agency expertise, he must include in the record specific examples of each practice mentioned in these regulations.

Regarding judicial review of regulations, the Commissioner notes that such review is assured by the Administrative Procedure Act whether the regulations are deemed interpretive or substantive. Judicial review is available in any enforcement proceeding brought against a particular manufacturer or product. Pre-enforcement review is also available. *Abbott Laboratories* v. *Gardner*, 387 U.S. 136 (1976). Thus, the Commissioner believes that the fears that substantive, binding CGMP regulations somehow deprive individuals of legal protections are unfounded.

As noted at the outset of this discussion, the Commissioner does not intend in the future to reconsider the legal authority of FDA to promulgate binding CGMP regulations under section 701(a) of the act, unless new material, not discussed above, is presented to him that raises substantial doubt as to the correctness of the analyses and conclusions he set forth above. For reasons discussed in this paragraph and in paragraph 36 below, the Commissioner has also decided that these CGMP regulations shall be issued as binding. The Commissioner advises that any person who still questions FDA's authority to do this is welcome to seek prompt pre-enforcement judicial review of this authority.

36. A number of comments suggested, in effect, that whether or not FDA could lawfully issue "binding" CGMP regulations, it would be unwise for the agency to do so. These individuals cited the complexity and variability of manufacturing control processes, emphasizing the variety of options available and the need for freedom of choice among these options by various manufacturers depending on cost and technological factors. They further complained that FDA lacked the expertise to determine which practices were best and that, by "freezing-in" techniques, FDA would discourage innovation and development of new procedures which might increase the assurance of product quality. The comments objected to the presumption that would follow from a technical violation of the CGMP regulations that the product was therefore adulterated and that individuals, under the legal doctrine of strict criminal liability under the Federal Food, Drug, and Cosmetic Act, were criminally responsible for these violations. Binding regulations would, in their opinion, provide the agency no flexibility for discretion in enforcement of the act. Finally, the comments objected that there was no need for binding regulations because there were only a few large pharmaceutical manufacturers involved in production of most drugs; because these were subject to frequent inspections by FDA; and because in the past, these firms had been subject to few problems, few recalls, and rare legal proceedings. This history suggested that most firms were in substantial compliance with the regulations regardless of whether they were classified as substantive or interpretive.

The Commissioner has evaluated these objections and found that, although some have merit, none is so serious as to outweigh the benefits from making CGMP regulations binding. Recognizing the diversity of manufacturing and control procedures, the Commissioner has endeavored wherever possible to state CGMP regulations in the terms of objectives to be attained, rather than methods of attaining such objectives. Procedures have been specified only where essential to assure product quality under the act. Thus, these regulations provide flexibility to manufacturers to select the methods and processes that will be most suitable to the products and operations of the individual firms. This flexibility should also permit the development of novel approaches to attaining the same objectives. In those few cases where precise procedures are set forth in these regulations, individuals who believe that alternative mechanisms may also be acceptable are invited to petition the Commissioner to amend the specific regulation to permit such alternatives.

As discussed in paragraph 35 of this preamble, the Commissioner does not believe that FDA lacks sufficient expertise to develop and promulgate CGMP regulations and advises that the public procedures for commenting on these proposed CGMP regulations, together with the opportunity to petition the agency for changes in the regulations, provide individual manufacturers with an opportunity to correct any errors in FDA's information. Thus, the Commissioner does not believe the agency lacks sufficient information to justify making CGMP regulations binding rather than interpretive.

With regard to the alleged lack of flexibility in the enforcement of "binding" CGMP regulations, the Commissioner believes that the comments have confused the question of whether a violation exists with the question of whether FDA will take action upon the violation. In numerous areas, FDA has established tolerances for actionable offenses and is currently in the process of establishing regulations setting forth agency policy with regard to prosecutions for violations of the act. It should be noted, however, that even in the absence of any CGMP regulations, whether binding or not, the doing of or failure to do any particular act which is inconsistent with current good manufacturing practice results in the product being legally adulterated, even if no legal action is brought. That is to say, the existence of CGMP regulations does not create violations of the law where they did not previously occur. The question rather is whether the violator will be prosecuted or enjoined and/or the product seized, an issue beyond the scope of this rule making.

Finally, with regard to the objection that there is no need to make these regulations binding since most major pharmaceutical manufacturers are in substantial compliance with the current regulations, the Commissioner believes that this is simply not relevant to the question of whether CGMP regulations should be binding or interpretive. The most significant justification for having the regulations binding is to minimize the burden on the government and on the courts in a case where a violation does occur. When the regulations are merely interpretive, the agency must provide expert testimony in each trial to demonstrate what the current good manufacturing practice in the industry is, notwithstanding the regulation. The cost of locating and preparing such expert witnesses and bringing them to the trial, as well as the judicial time taken in hearing these witnesses, would be eliminated by having binding regulations. In the event that a challenge is raised about the validity of the regulation, FDA can present to the court the administrative record underlying the regulation in lieu of any expert testimony. Thus, it is not the proportion of manufacturers who are in compliance with the regulations but the number who are out of compliance and whose noncompliance justifies regulatory action that necessitates making these regulations binding. For these reasons the Commissioner has concluded that insofar as he has discretion to issue CGMP regulations as either binding or

interpretive, he elects to make them binding.

37. Several comments suggested the words "where applicable" be inserted in the first sentence of § 210.1(a). The comments argued that, as proposed, the CGMP regulations would require conformance to every requirement regardless of the need to do so.

The Commissioner concludes that there are numerous examples of flexibility built into the CGMP regulations. Words like "appropriate" and "as necessary" are used in the regulations to make it clear that requirements which are not relevant to a given manufacturer's operation do not apply. In addition, a new paragraph (b) is established in § 210.2 to clarify that the requirements apply only to those operations subject to the CGMP regulations in which the manufacturer is engaged.

38. Two comments recommended that the references in this section be Parts 210 through 226 instead of Parts 210 through 229, since § 229.25 was being revoked.

Since the Commissioner has reserved all parts between 210 and 229 for current good manufacturing practice regulations, the reference is appropriate. Even though § 229.25 has been revoked, Part 229 may be used in the future.

39. One comment suggested insertion of the phrase "and testing and quality control thereof" after the words "the manufacture, processing, packing, or holding of a drug product" in § 210.1(d).

Because "manufacture, processing, packing, or holding of a drug product" is defined in § 210.3(b)(12) to include testing and quality control of drug products, the Commissioner rejects this comment.

40. A large number of comments recommended that the personal liability statement in § 210.1(b) be eliminated. Some comments suggested that an individual should be held responsible only if actual contamination has occurred. Others recommended modifying the liability statement by requiring willful and knowing intent to violate the law. One comment said this was unclear as to who was covered by the section and that it was not useful in clarifying the requirements of the act. Another asked about the definition of "responsible."

The Commissioner notes that actual contamination of a drug does not have to occur for the article to be deemed adulterated under section 501(a)(2)(B) of the act. Further, the act does not require a showing of intent for a person to be held accountable under the act. *United States* v. *Dotterweich*, 320 U.S. 277, (1943); *United States* v. *Park*, 421 U.S. 658 (1975). It would be contrary to public policy and congressional intent, as well as beyond the Commissioner's authority, to require the showing of actual contamination or intent. Congress purposely did not do so in order to provide the maximum protection of the public health.

With regard to clarifying "person," the Commissioner advises that the word "person" is defined in section 201(e) of the act to include corporations and partnerships as well as individuals. Under section 301(d) of the act, the adulteration of any drug is a prohibited act, and under .section 303(a) "any person who violates a provision of section 301" is subject to criminal penalties. Thus, the reference to "the person" in § 210.1(b) merely parallels the statutory language. The reference to the word "responsible" is in accord with interpretations of the act by the Supreme Court of the United States. See *United States* v. *Park*, 421 U.S. 658 (1975). Thus, the Commissioner does not believe that this language is unclear or misleading. He also believes that, although § 210.1(b) is not essential to the regulations and merely reflects the legal position of the agency, it is a useful exposition of FDA policy with regard to failure to comply with the CGMP regulations. For this reason, the language is retained in the final order.

41. One comment said the CGMP regulations, as proposed, set up FDA as both prosecutor and judge and deprive persons of due process.

The Commissioner finds that penalties for violation of these regulations (i.e., seizure of violative products, injunctive sanctions, and criminal prosecution) are imposed by judicial proceedings in United States courts, where the U.S. Department of Justice serves as prosecutor, Federal judges preside, and in criminal cases there is a right to trial by jury. The role of FDA is twofold: First, it establishes standards amplifying the statutory language (through issuance of CGMP regulations after public comment); and second, it investigates to determine whether these standards have been violated. Affected persons have full legal rights, including the right to challenge the regulations as being beyond the authority of the act. The Commissioner finds no rationale to suggest these CGMP regulations compromise any person's right to due process.

VI. Applicability of CGMP Regulations; Exemptions

42. Many comments said there should be exemptions or waivers from the CGMP regulations for certain classes of drugs or specialized kinds of manufacturing activities. These comments came from manufacturers of bulk drugs, veterinary drug products, radiopharmaceutical drug products, biological drug products, so-called "drug-cosmetic" products, and wholesalers and retail dispensers of drug products. These comments, except one, asserted that the CGMP regulations were inappropriate, unnecessary, excessive, or not part of current industry practice when applied to the type of product identified; the exception (discussed in paragraph g. below), together with one comment regarding a particular product line, questioned FDA's legal authority to apply CGMP regulations to certain types of businesses or products.

As discussed in the preamble to the February 13, 1976 proposal, the Commissioner intends to propose at future times CGMP regulations for specific classes of drug products such as small volume parenterals, compressed medical gases, and radiopharmaceuticals. (See, e.g., the proposal regarding LVP's published in the Federal Register of June 1, 1976 (41 FR 22202).) In addition, regulations for certain kinds of manufacturing activities such as manufacturing of bulk drug components, repacking, or relabeling will be proposed. Generally, these future regulations will supplement, and in some situations supersede, the more general CGMP regulations. As these proposals are issued, the need for waivers from or modifications in the general CGMP regulations should be diminished.

After considering these plans and the comments regarding exemptions for specialized drug products or manufacturing activities, the Commissioner has reached the following conclusions:

a. *Bulk drugs.* It is first necessary to distinguish between (1) "drug products" (i.e., finished dosage forms) that may be held in bulk containers, and (2) bulk drug "components" (i.e., ingredients intended for use in the manufacture or processing of a drug product). The CGMP requirements set forth in Part 211 are intended to apply to the preparation of a finished dosage form, whether or not in packaged form. This is clearly set forth in the regulations (§§ 210.3(b)(4) and 211.1(a)). Although these CGMP regulations are not applied to the manufacture of bulk drug components, there are numerous instances where good manufacturing practices for bulk drug components would parallel the requirements set forth in Part 211. For this reason. FDA will utilize the standards of Part 211 as guidelines during inspections of manufacturers of bulk drug components under the jurisdiction of the act.

b. *Veterinary drug products.* Veterinary drug products shall continue to be subject to the general CGMP regulations for all drug products, with certain specific exceptions, namely §§ 211.42(d), 211.46(d), and 211.72. Comments regarding the appropriate-

ness of individual provisions of these regulations to veterinary drug products have been considered and responded to under the sections involved. When the provisions of a section in the regulations do not apply to veterinary drug products, exemptions for such products are stated in that section.

c. *Radiopharmaceutical drug products.* The general CGMP regulations are suitable requirements for the preparation of radiopharmaceutical drug products. When the Commissioner was aware of situations where the requirements are not appropriate, exemptions were made from these final regulations. Supplemental requirements specific for radiopharmaceuticals will be proposed in the future.

d. *Biological drug products.* The Commissioner notes that section 902(c) of the act parallels section 351(g) of the Public Health Service Act (42 U.S.C. 262(g)), which provides that section 351 does not affect, modify, repeal, or supersede the Federal Food, Drug, and Cosmetic Act. The agency has consistently interpreted these provisions to be additive; that is, although they preclude duplicative or inconsistent regulation under the two acts, where one statute speaks to a matter regarding biological products and the other statute is silent, the express statutory provisions govern, regardless of the statute in which they appear. Thus, for example, the provisions of section 505(i) of the act regarding investigational use of new drugs have been consistently held to apply to biological products because no part of section 351 of the Public Health Service Act addresses investigational use of biologics (21 CFR 312.1(g)). Because section 351 of the Public Health Service Act does not refer to current good manufacturing practice and because biological products are considered to be drugs subject to section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, the Commissioner believes it is consistent with both laws to apply current good manufacturing practices to biological drug products.

Biological products are now manufactured according to current good manufacturing practice and regulated under parts 600 through 680 (21 CFR parts 600 through 680), in particular the establishment license and product license provisions. Sections 210.2 and 211.1 clearly provide that the more specific biologic regulations prescribed in 21 CFR Parts 600 through 680 will supplement or supersede, where appropriate, the more general drug CGMP regulations. The Commissioner believes it possible that provisions in the general CGMP regulations may be inappropriate for certain biological products and would make appropriate changes to assure that the CGMF requirements would not increase manufacturing costs without a commensurate increase in safety, purity, potency, or efficacy. However, no specific examples were submitted to FDA in response to the proposal that can be considered as areas for exempting biological drug products. The Commissioner invites interested persons to submit petitions under § 10.30 to amend particular provisions of the CGMP regulations to account for the special technologies or incompatabilities of biologics.

e. *Compressed medical gases.* The agency will propose specific CGMP regulations for compressed medical gases. Until such regulations can be proposed for public comment, comments received and evaluated, and a final regulation published, however, the Commissioner concludes that the requirements in the more general CGMP regulations, with certain stated exceptions, are applicable. It would not be in the public interest to delay a final regulation based on the February 13, 1976 proposal until FDA can promulgate specific CGMP regulations for compressed medical gases.

f. *Repackaging and relabeling.* Only certain portions of the general CGMP regulations apply to repackaging and relabeling operations. For example, the requirements pertaining to labeling control apply to repackers and relabelers, while the requirements for compounding a drug product do not apply since repackers/relabelers do not compound drug products. The CGMP regulations apply to repackaging and relabeling operations at locations that are different from the place of manufacture. Supplemental CGMP regulations regarding this unique type of drug processing will be proposed in the future.

g. *Wholesalers.* Section 501(a)(2)(B) of the act provides that a drug shall be deemed to be adulterated if "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to current good manufacturing practice * * *." This section, through the operation of section 301(k) of the act, applies to wholesalers, retailers, pharmacies, and hospitals, as well as to manufacturers. However, the CGMP regulations set forth in part 211 apply only to establishments engaged in the preparation of a drug product. Therefore, these regulations do not apply to the wholesalers, retailers, pharmacies, and hospitals engaged in activities that are traditional to those establishments. The wholesaler, however, is a particularly important link in the distribution chain between manufacturer, retailer, and consumer. The Commissioner encourages wholesalers to adopt applicable provisions of the CGMP regulations to insure that drug products are handled and stored in a manner that will not contribute to loss of identity, strength, quality and purity. In addition, they are responsible for being able to identify the distribution of drug products that are subject to recall or market withdrawals. Recall strategy will frequently involve wholesalers as consignees and intermediate distributors when recalls are to the retail or consumer levels. In the FEDERAL REGISTER of June 16, 1978 (43 FR 26202), FDA published regulations to provide guidance to manufacturers and distributors in this area. It is especially important for wholesalers to maintain adequate records to assure effective recall or market withdrawal. If future experience indicates to FDA that recalls and market withdrawals are being adversely affected by inadequate recordkeeping on the part of the wholesalers, the Commissioner will give further consideration to the need for specific CGMP regulations for wholesalers.

h. *Drugs that are also cosmetics.* A number of comments, including a petition to the Commissioner, were received regarding the applicability of the proposed general CGMP regulations to a class of products identified as "cosmetic-drug products" and described as those which: (1) Meet the definitions of both "drug" and "cosmetic" under section 201 of the act; (2) represent a minimal health or safety risk; and (3) are marketed over-the-counter for regular and frequent consumer use without dosage limitations. Examples of these products were described as medicated skin creams, antibacterial soap, antiperspirants, and topical sunburn prevention products. Specifically, the comments requested separate CGMP regulations for this alleged class of drugs, and one comment submitted a proposed new part 213 for drug-cosmetic products, drafted in the style and format of other CGMP regulations for drugs. Another comment recommended that, because the drug-cosmetic products were so similar to related cosmetic products, CGMP regulations for those two classes of products be proposed and adopted together, separate from those relating to drug products generally.

The Commissioner has concluded that these regulations, except expiration dating for certain human OTC drug products described in paragraph 353 of this preamble, must apply to all products meeting the definition of drug products, whether the drug products are highly potent prescription drugs or are OTC drugs of the type described as "cosmetic-type." Past experience of the agency has demonstrated that the public has been put in a hazardous situation because of manufac-

turing errors in OTC products, such as by the substitution of spirits of camphor for castor oil. Further, the Commissioner notes that there are very few clearly innocuous drug products or components in the OTC area. Several examples can be given: If appropriate stability study requirements and manufacturing controls required by CGMP regulations are not met for fluoride toothpaste, there could be a question of effectiveness of the products because of the unavailability of fluoride in a toothpaste. In the case of aerosolized products, control of the particle size and identity and purity of components are important for the safety of the user. In the case of topical cosmetic-type drugs, the incidence of allergic reactions may be lessened by the assurance of uniform quality of these products. That many of the general CGMP regulations are applicable to and reasonable for cosmetic-type drug products is evidenced by the fact that a majority of the specific suggestions submitted by the petitioner and others as applicable for cosmetic-type drug products duplicated in substance, a number of comments submitted by other OTC manufacturers and manufacturers of prescription drug products and the proposed text of part 211.

Although he declines to provide a broad exemption for cosmetic-type drugs products, the Commissioner points out that a number of changes proposed by the comments are adopted in the final regulations. These suggested changes were appropriate for application to the manufacture of all drugs products, however, and not merely cosmetic-type drug products. In many instances the suggested changes that were adopted do not alter the original intent of the regulations, but clarify it or provide flexibility in complying. In a few cases, the proposed requirements were deleted or changed where the Commissioner concluded that they were not necessary to assure the quality of drug products, cosmetic-type or otherwise.

i. *Drug products that are also foods.* Although no specific requests were received to exempt OTC drug products that are also human foods from Part 211, the Commissioner has tentatively concluded that there may be a few such products that would more appropriately be regulated under the good manufacturing practice regulations for food. He believes that the type of OTC drug products that could be exempted from Part 211 are those that are ordinarily marketed and consumed as human foods which may also fall within the legal definition of drugs by virtue of their intended use. Therefore, elsewhere in this issue of the FEDERAL REGISTER, the Commissioner is proposing to exempt such products if the products and all their ingredients are ordinarily consumed as human foods. Examples of products that the Commissioner foresees being covered by the proposed exemption are (1) Some candy cough drops formulated entirely of ingredients ordinarily consumed as human foods or ingredients of human foods; and (2) sodium bicarbonate labeled for use as an antacid but ordinarily use as an ingredient of human foods under the more common "baking soda" label. In proposing this exemption for certain OTC drug products, the Commissioner has considered, first, the inadvisability of applying drug CGMP regulations that are not necessary to ensure appropriate quality characteristics in view of the intended use of a product and, second, the reasonableness of applying food GMP regulations to a product manufactured, handled, and ordinarily consumed as a human food.

Therefore, the Commissioner has stated under § 211.1(c) that, pending considered of the proposal, the requirements of Part 211 will not be enforced for OTC drugs that meet the proposed definition. During the interim and until further notice, regulations under Part 110 (21 CFR Part 110) and, where applicable, Parts 113 to 129 (21 CFR Parts 113 to 129) shall be applied in determining whether these products are manufactured, processed, packed, or held under current good manufacturing practice.

43. One comment from a university school of pharmacy asked whether future proposed CGMP regulations would specifically state their applicability to such situations as (1) personnel at hospital "A" strip-packaging drug products for its own use as well as for use in hospitals "B" and "C"; (2) personnel at the warehouse of a chain of pharmacies who repackage and relabel quantities of drug products from manufacturers' original commercial containers for different units in the drug store chain; and (3) similar repackaging and relabeling by individual pharmacists as members of informal buying groups.

As noted in paragraph 42(g) above, section 501(a)(2)(B) of the act applies to retail establishments, pharmacies, and hospitals, but the specific regulations in Part 211 do not. When CGMP regulations for repackers and relabelers are proposed, some of these questions posed in the comment will be addressed. Regarding pharmacies and hospitals in particular, however, it is the policy of FDA not to inspect routinely for compliance with section 501(a)(2)(B) of the act establishments that operate within State or local laws governing the practice of pharmacy. Nor has FDA ever sought to issue specific CGMP regulations for pharmacies engaged in traditional activities of dispensing or selling drugs at retail. This policy is consistent with statutory exemptions provided for pharmacies regarding establishment registration in section 510(g) of the act and regarding establishment inspection in section 704(a) of the act. When a hospital or pharmacy is engaged in drug repacking or relabeling operations that are beyond the usual conduct of dispensing or selling drugs at retail, however, the exemptions in the act cease to apply; the establishment is required to register and is subject to regular inspections under section 704 of the act. Furthermore, appropriate current good manufacturing practice must be complied with.

44. Several comments expressed concern about the applicability of CGMP regulations to foreign drug manufacturers. One comment said foreign drug manufacturers may not uniformly be subject to the stringent controls of United States manufacturers and that sampling of foreign drug products at the point of importation is not sufficient to assure the quality of those drugs. Two foreign drug manufacturers indicated that CGMP regulations had a significant impact on their operations. Another foreign manufacturer said their facilities were inspected annually by FDA with respect to antibiotic certification and new drug approvals.

The act applies to drugs introduced into interstate commerce in the United States, including drugs imported from other countries. It does not, of course, apply to manufacturing of drugs in other nations if the drugs are not brought into the United States. Many foreign countries, however, have adopted requirements similar to CGMP regulations, and foreign manufacturers may be subjected to inspection by their own governments. International organizations such as the World Health Organization and the European Free Trade Association provide manufacturing standards and reciprocal agreements between participating countries. Overseas pharmaceutical manufacturers who export to the United States are inspected by FDA or under reciprocal inspection agreements as part of the new drug application approval process and antibiotic drug certification, and individual drug products are subject to intensive examination, including testing, before being allowed into the United States. If, for example, there is a question regarding the safety, identity, strength, quality, or purity of a drug product offered for import, FDA has authority to deny entry of the article unless factory inspection is permitted or inspectional information is available about those firms covered under reciprocal inspection agreements. The United States currently has reciprocal inspection agreements under which govern-

ments will exchange inspection information about domestic firms in lieu of conducting overseas inspections. These agreements are with Sweden, Switzerland, and Canada. Therefore, the Commissioner finds that there is adequate coverage of imported drugs to assure compliance with CGMP regulations.

45. Several comments referred to provisions in the Medical Device Amendments of 1976 and requested that FDA consider providing for exemptions from or variances to the CGMP regulations and special advisory assistance as Congress specifically mandated regarding FDA regulation of small manufacturers of medical devices. Along the same lines, a substantial number of comments were received from "small" drug manufacturers or organizations representing "small" drug manufacturers who strenuously oppose most of the proposed changes in the CGMP regulations. The tenor of the majority of the comments was that the proposed changes would seriously affect the initial and continuing costs of a "small" drug manufacturer but probably have little economic impact on, or could more easily be absorbed by, a "large" pharmaceutical manufacturer. Several comments expressed concern that generic drug manufacturers might be eliminated because they could not meet all the requirements of the proposed CGMP regulations and still compete in the marketplace. Arguments were presented that, because small manufacturers very often are involved with the manufacture of a small number of products (frequently less potent over-the-counter preparations) and almost by definition have small physical facilities, limited equipment, and few personnel, extensive formal quality control procedures are unnecessary to assure high quality of the drugs manufactured. One comment, apparently from a small manufacturer, agreed in principal with the proposed CGMP regulations, felt that size had very little to do with achieving good manufacturing practice, and offered comments on specific sections of the proposed CGMP regulations.

The Commissioner rejects the contention that quality control procedures are unnecessary in the case of small firms; FDA's experience is that quality control procedures falling below those described in these regulations, in firms of great or small size, are often responsible for lack of drug product quality. The Commissioner also rejects the argument that less control need be exerted over so-called "less potent over-the-counter preparations," which respondents stated are often manufactured by small firms, for the reasons explained in paragraph 42(h) above.

The Commissioner believes that the final regulations will be no more burdensome for small manufacturers than for others. Many interpretations offered in comments on specific sections strongly suggested that the intent of the proposed regulations had been misunderstood. The language has been clarified in the final regulations. In other instances the requirements were reworded to provide for more flexibility for the varieties of procedures and controls that may be utilized by various manufacturers.

The Commissioner does not believe a specific provision within the CGMP regulations for variances to these regulations is necessary for small manufacturers. A mechanism already exists, however, in 21 CFR 10.30 for firms to petition for variances to or amendments in any regulation when the requirements are not reasonably attainable.

For many years FDA has conducted and participated in numerous seminars and workshops designed to assist drug firms in interpreting and carrying out the requirements of CGMP regulations. Additionally, the agency has made films and publications available that are also designed to assist drug firms in their efforts to comply. The agency is committed to continuing these voluntary compliance efforts especially designed to assist small businesses.

46. Several comments noted that the current good manufacturing practice regulations do not pertain to veterinary biological products. One respondent suggested that the section specifically state that these regulations apply only to human biological products.

The Commissioner believes that the section as proposed clearly establishes applicability to pertinent biological drug regulations, but for consistency with references elsewhere in the CGMP regulations to human biological drug products, he is revising § 210.2 to specifically include reference to biological drug products for human use.

47. Several comments requested clarification of the last sentence of § 210.2 to show that conflicting or contradictory regulations would be superseded by the one specifically applicable to the drug product.

The Commissioner finds that the proposed wording clearly states his intent. Certainly, in the case of conflicting or contradictory regulations, it will be impossible to comply with all regulations and the regulation that is specifically applicable to the drug product in question would apply.

48. A comment suggested that if medicated premixes are meant to be excluded from Part 210, then Part 226 should be specifically excluded.

The meaning of this comment as it relates to § 210.2 is not clear. The Commissioner advises that Part 210 applies to all the regulations in Parts 211 through 229.

49. One person proposed that the term "drug product" be replaced with the words "commercial dosage form" to exempt drugs undergoing development from the requirements of these regulations.

The Commissioner finds that, as stated in § 211.1, these CGMP regulations apply to the preparation of any drug product for administration to humans or animals, including those still in investigational stages. It is appropriate that the process by which a drug product is manufactured in the development phase be well documented and controlled in order to assure the reproducibility of the product for further testing and for ultimate commercial production. The Commissioner is considering proposing additional CGMP regulations specifically designed to cover drugs in research stages.

VII. Definitions

The Commissioner received hundreds of comments regarding definitions. General comments are listed immediately below; comments regarding specific definitions follow in numerical order.

50. One respondent said this section is inconsistent because certain terms such as "drug" and "establishment" which are defined in the act are not defined here, while other terms which are defined elsewhere are also defined here.

The Commissioner believes that the length of part 210 would be unnecessarily increased by including in this part the definitions of terms that are well known or already defined in the act. Other terms the meaning of which may not be as readily recognized, or may vary in other regulations because of context and needs, are defined in part 210 as a standard reference.

51. One comment suggested that all terms defined in part 210 be highlighted in the running text.

The Commissioner is not convinced that highlighting defined words in the running text offers any advantages over the more usual manner of printing. For example, some persons might interpret highlighting as adding emphasis that is not intended to a particular word or phrase. This suggestion cannot be adopted.

52. One respondent suggested rules for selecting words to be defined, namely: (1) Words which will be used in a sense differing from that given in the currently accepted dictionaries and (2) words whose meaning will be limited by the regulation.

The Commissioner believes the above criteria have been generally used for selecting terms to be defined. He does not wish, however, to limit strictly the criteria for determining the terms to be defined in this part.

53. Several comments asked that commonly used terms such as "drug product containers," "labeling," and "production area" be defined.

The Commissioner finds that either the terms have already been defined elsewhere (e.g., "labeling," which is defined in section 201(m) of the act) or they are generally well understood and need no further definition (e.g., "drug product container"). He concludes that no further definitions need to be added at this time.

54. One comment suggested that "cycle of manufacture" be defined in § 210.3(b)(2) as "any period of time in which the batch is not adversely altered."

The Commissioner has considered this comment, but does not find that the suggested wording offers any advantage. The definition, as it appeared in the proposal, has been in the CGMP regulations for a number of years. The Commissioner is confident that this definition is well understood.

55. Several comments suggested modification of the term "batch" in § 210.3(b)(2) by addition of the words "is intended to have" before "uniform character." Another modification suggested was a new phrase at the end of the sentence: "Which is accepted and offered for sale or distribution."

In defining a "batch," the Commissioner has adopted the phrase "intended to have uniform character and quality." Using the phrase "intended to have" in the definition allows the use of the term "batch" without having to distinguish between acceptable and unacceptable batches. If a manufactured batch does not have uniform character and quality within specified limits, then the batch becomes an unacceptable or a rejected batch. The Commissioner rejects the phrase "which is accepted and offered for sale or distribution." Those batches which are manufactured but never intended for sale or distribution may be designated as trial or experimental batches by the manufacturer.

56. Three comments on § 210.3(b)(3) requested that the term "component" be changed to "ingredient," stating that the former term has been used in the drug industry for "packaging supplies."

The Commissioner recognizes that the term "component" is broadly used in the English language and may have a variety of meanings. However, the definition of this term in the proposal has been in effect for a number of years and the Commissioner believes it is generally well understood. Because only three comments were received regarding this particular issue, the Commissioner concludes that the drug industry generally does not find the term misleading. Therefore, the recommendation is not adopted.

57. A suggestion was made that the definition for the word "component" in § 210.3(b)(3) should include gases and filters, because these items need additional control when used in the manufacture of injectable products.

The Commissioner notes that "component" includes gases that are used as ingredients. He believes filters are more appropriately classified as equipment. The Commissioner believes that control of gases and filters is adequately set out in the regulations.

58. One comment suggested that the definition for "component" be expanded to include the phrase "raw material, chemical compound, drug substance or pharmaceutic ingredient."

The Commissioner agrees that the above items when used as ingredients are properly classed as components. It is not necessary or desirable, however, to list each type of material that may become a component under the regulations, because items other than those identified in the comment may also be "components." Therefore, the suggestion is not accepted.

59. A suggestion was received to include the following phrase after the word "manufacture" in the second sentence of § 210.3(b)(3): "of finished dosage form, e.g., tablets, capsules, solutions, etc."

The Commissioner rejects this suggestion. The term "drug product" is defined in paragraph (b)(4) of § 210.3 as "a finished dosage form" and restatement of the definition is inappropriate.

60. Several comments requested clarification of the relationship among the definitions in § 210.3(b) (3), (7), and (8) of "component," "active ingredient," and "inactive ingredient." Comments expressed concern that proposed definitions of the types of ingredients do not include all materials comtemplated under the definition of "component."

The Commissioner finds that the definition for "inactive ingredient" in § 210.3(b)(8) should be modified so that it clearly includes "any component other than an active ingredient." He believes this change will eliminate any misunderstanding of these definitions.

61. One comment suggested that the term "drug product," as proposed in § 210.3(b)(4), could be interpreted to mean only the finished packaged unit.

The Commissioner finds that the term is defined as meaning "finished dosage form" regardless of whether it is in package form.

62. A comment was received stating that the term "drug product" as defined in § 210.3(b)(4) excludes placebos because the definition includes the phrase "active drug ingredient."

The intended use of placebos in medical treatment is to bring about a therapeutic effect, without a pharmacologically active agent, because of the psychic effect in some patients that may produce symptomatic relief. In addition, it is often used as a control in clinical trials for new drugs. Even though the chemicals from which the placebos are made are not intended to cause a direct pharmacologic response, the maintenance of their quality is important because of their use in patients, particularly in controlled drug studies. By its use, a placebo meets the definition of a "drug" contained in section 201(g) of the act. Therefore, to eliminate any doubt whether these regulations apply to placebos, the Commissioner has revised the definition to include them specifically.

63. A number of comments questioned the definition of "fiber" in proposed § 210.3(b)(5). The comments were that "fiber" had been defined arbitrarily and without scientific basis; that the definition was too general and could include, for example, crystal, metal and splintered wood; and that the definition should include dimensional parameters for the fiber size. Comments recommended that the definition include morphological descriptions such as threadlike, filamentous, amorphous or noncrystalline, cellular, foreign, and hairlike. Several comments recommended that the American Society for Testing and Materials definition be used. Others suggested that a length of at least 100 microns and a length/width ratio of 10 to 1 be adopted. One comment called for adopting a minimum length of 10 microns and a diameter one-tenth the length.

The Commissioner finds that the term "fiber" has not been defined arbitrarily and without scientific basis. The basis for the fiber definition was discussed in the final regulations for asbestos-form particles in drugs for parenteral injection, which appeared in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865). (Those final regulations reference the definition of "fiber" appearing in "Occupational Exposure to Asbestos," criteria document, U.S. Public Health Service, National Institute for Occupational Safety and Health, Chapter VIII, p. 6, 1972.) The Commissioner believes that the definition should be as broad as possible and that the suggested morphological descriptions and dimensional parameters are unnecessary and in many instances are not informative. Dimensional parameters were intentionally left out because current

knowledge is limited as to what size fiber does not constitute a hazard. Furthermore, the suggested fiber length of at least 100 microns is unacceptable because most asbestos fibers released from asbestos-cellulose filters are less than 70 microns in length.

The American Society for Testing and Materials' specifications (ASTM Manual F24-65, Standard Methods for Measuring and Counting Particulate Contamination on Surfaces) for defining "fiber" are not pertinent to the subject at hand. They were developed specifically for particles on surfaces of mechanical objects as related to abrasion of such objects.

To eliminate any concern that the definition of fiber would include particles intentionally present, as in drug suspensions, the final regulation is modified by adopting the concept of particle contamination. Therefore, fiber means any particulate contaminant having a length at least three times its width.

64. Comment was received regarding § 210.3(b)(6) that the definition for "non-fiber-releasing filter" should include the concept of a filter "being designed" not to release fibers after appropriate pretreatment. Another comment said a requirement for non-release of fibers is unrealistically absolute, i.e., no known filter could meet the definition.

The Commissioner advises that the final regulation adopting the definition for "non-fiber-releasing filter," published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865), addressed similar issues. In responding to comments in that document, the Commissioner concluded the definition should include the concept that after appropriate pretreatment such as washing or flushing, the filter will not continue to release fibers into the drug that is being filtered. The design concept is therefore taken into account because of the distinction made between filters which release fibers by media migration, i.e., continuous release due to the nature of the filter, and filters which contain fibers from structural supports and contamination.

With regard to the comment that the requirement for nonrelease of fibers is unrealistically absolute, the Commissioner finds that the definition clearly describes types of fibers that are relied upon in the industry as "non-fiber releasing." The Commissioner concedes that any filter may release an occasional particle, some of which may meet the definition of "fiber" under § 210.3(b)(5). The purpose of the definition for "non-fiber releasing filter," which has been applied for over 2 years without apparent misunderstanding, is to provide a reasonable and practical description of a filter that may be fabricated from a number of different materials and will not, in the ordinary sense, introduce fibers into the drug product during filtration.

As discussed in detail in the preamble to the March 14, 1975 final regulation adopting the definitions for "fiber" and "non-fiber releasing filter", FDA is studying several issues invoving fiber contamination and the effects on humans to fiber exposure. Until such time as the Commissioner has obtained sufficient information to alter his position on fiber contamination in parenteral drug products without adversely affecting the public health, he concludes that the definition for "non-fiber releasing filter" continues to be appropriate for these regulations.

65. Comment was received that the definition of "non-fiber-releasing filter" as written in § 210.3(a)(6) would discourage the development of asbestos filters that might not be fiber releasing.

The Commissioner advises that it is not the intention of FDA to discourage the development of asbestos filters. In this regard, the preamble to the final order in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865) addresses this issue in detail.

66. One comment suggested that "non-fiber-releasing filter" be redefined to apply only to the final filtration of components and drug products.

The Commissioner concludes that the suggestion would allow use of an asbestos filter for filtration of in-process materials. This use of asbestos filters is unacceptable, except under the provision of § 211.72(b), and would defeat the purpose of the regulation.

67. A comment suggested that after the word "component" in § 210.3(b)(7) the phrase "other than veterinary biological immunizing or diagnostic agent" should be added.

The Commissioner finds that articles that are not deemed drug products or that are not under the jurisdiction of the act are not subject to these regulations. It is not desirable or feasible to identify in these regulations every specific class of articles that are not subject to CGMP regulations. Veterinary biologicals have, however, been excluded by changes in § 210.2. When an interested person has a question regarding the status of another individual product or class of products (for example, the status of an article that may be either a drug or a device), that person may obtain a formal opinion from FDA pursuant to 21 CFR 10.85.

68. Several comments asked that limits be placed on the term "in-process materials" defined in § 210.3(b)(9) in order to restrict it to those materials generated "in-plant" as opposed to those materials acquired from an outside source.

The Commissioner agrees that the term "in-process materials" is intended to apply to materials being processed by establishments engaged in the preparation of a drug product. He believes this intent is clear when the term is considered in the scope of these regulations and that no change is needed.

69. Several comments requested clarification whether the term "in-process materials" in § 210.3(b)(9) includes labels printed "in-house" and other "nonchemical" items.

It was not the Commissioner's intent that "in-process materials" include label printing. The regulations do not suggest that such labeling would constitute in-process materials. References to labeling materials are clearly stated in these regulations when appropriate.

70. One comment suggested that the word "materials" in § 210.3(b)(9) be changed to "ingredients."

The Commissioner concludes that the term "in-process materials" is in current usage and sees no advantage to introducing the suggested term "in-process ingredients."

70a. One comment stated that § 210.3(b)(9), and especially the word "fabricated," is unclear and should be further defined to eliminate any possible confusion.

The Commissioner does not agree that the word "fabricated" is unclear when used in this definition. This suggestion is rejected because a broad term such as "fabricated" is appropriate here.

71. Several comment said, in the case of biologics, a "lot" may consist of more than one batch and suggested that this be included in the definition of "lot" in § 210.3(b)(10).

Because the term "lot" has already been defined specifically for biological products in 21 CFR 600.3(x), the Commissioner does not believe that any modification of the definition in this part is appropriate. As previously indicated, the more specific regulations for biological drug products take precedent over the more general.

72. Two comments said the term "lot" was used elsewhere in the CGMP regulations (e.g., § 211.84(a)) to refer to containers and closures, which are neither drugs nor drug products. They said either the definition in § 210.3(b)(10) or the reference was incorrect.

The Commissioner notes that the definition in § 210.3(b)(10) refers to the term "drug product," but does not limit to drug products the applications of the definition for "lot." However, the proposed definition for "batch" is limited to drugs. Because a lot is defined as a batch or portion of a batch,

the definition for "batch" is expanded to include materials other than drugs. Similarly, the definition for "lot number" is expanded to include other materials.

73. One comment said the definition for "lot number" in § 210.3(b)(11) unnecessarily ruled out the use of symbols.

It was not the Commissioner's intent to preclude the use of symbols, and the definition is modified accordingly.

74. One comment suggested deletion of the word "complete" from § 210.3(b)(11) as superfluous and subject to interpretation.

The Commissioner finds that use of the phrase "complete history" emphasizes that pertinent identifying information is included.

75. Two comments suggested that the words "testing, and quality control of drug products" be deleted from the definition in § 210.3(b)(12). One said these functions do not belong in this definition because they introduce ambiguities elsewhere in the proposed regulations. Examples given are: (1) § 211.103, which requires yield determination at the end of each distinct phase of manufacturing; and (2) § 211.67(b), which requires that procedures describe a cleaning schedule for all equipment used in manufacturing, processing, packaging, or holding of a drug product. The respondent said yield calculations and cleaning schedules do not apply to laboratory testing and equipment. Another respondent said the words "testing and quality control of drug products" should be deleted because they conflict with the concept of independent responsibility for quality control and manufacturing functions.

The Commissioner sees no ambiguities arising from the inclusion of "testing and quality control of drug products" in this paragraph. Indeed, comments were received on numerous sections of the regulations (e.g., §§ 211.2 (recodified § 211.68) and 211.25) to add the phrase after references to "manufacture, processing, packing, and holding." In all cases, the Commissioner has declined to make the addition. The purposes of this definition are to make it clear that the phrase "manufacture, processing, packing, or holding of a drug product" includes operations that are commonly known by other terms such as "packaging," "labeling," or "quality control," and to eliminate the need for inserting references to testing and quality control throughout the text of these regulations. Section 211.103 is modified to provide that yield determinations are not required for quality control activities. The Commissioner believes, however, that the requirements of § 211.67(b) are appropriate for quality control operations.

The Commissioner believes that the functions of quality control and manufacturing can be included in the total concept of producing drug products and still be independent. The comment did not describe how the definition would actually cause a loss of independence of the quality control function.

76. One comment suggested that the term "warehousing" was more suitable than the term "holding" in § 210.3(b)(12).

The Commissioner finds that, although the term "warehousing" describes the meaning intended some of the time, the more general term "holding" is more suitable. The Commissioner also notes that the entire phrase "manufacture, processing, packing, or holding" is repeated from section 501(a)(2)(B) of the act.

77. One comment said the term "quality control" is too vague in § 210.3(b)(12) because it does not cover the responsibilities of other than the quality control department. The comment suggested the following wording: "Manufacturing, processing, packaging or holding of a drug product includes packaging and labeling operations, testing and other measures taken to insure that the drug product has the identity, strength, quality and purity which it purports to or is represented to possess."

The Commissioner does not agree that the definition is vague. The intent is to identify several key operations that might not be perceived as an integral part of the production of pharmaceuticals, but for purposes of CGMP regulations must be included. It is not necessary, however, to describe every operation that is included under the act. The responsibilities of the quality control unit are specified in § 211.22 and are not affected by this definition.

78. Several comments said the definition in § 210.3(b)(15) of a "quality control unit," taken together with its responsibilities, would mean that the quality control unit would duplicate functions such as engineering, which are better handled by other professionals such as engineers. They also said the term "unit" generated confusion vis-a-vis the "quality control department" and "quality assurance department." Another comment said the word "perform" should be replaced with "be responsible for."

Functions that are properly those of the engineering department or other specialized units because of their unique training and expertise should not be duplicated or usurped by the quality control unit. Where expertise is in other units, the responsibility of the quality control unit is to assure that such expertise has been utilized. In order to make clear that quality control functions may be performed by persons assigned to units outside the quality control unit, the Commissioner is replacing "perform" with "be responsible for." The quality control unit will still have the duty to assure that appropriate actions were implemented and completed satisfactorily. The Commissioner used the word "unit" because it is a term broadly applicable to any group within a manufacturing establishment charged with the responsibility of quality control. The Commissioner is not concerned about the name given by a firm to its own unit that is responsible for quality control functions.

79. Several comments suggested use of the term "expected yield" instead of "theoretical yield" in § 210.3(b)(17) and in § 211.192. They also suggested that the definition include a provision for normal and expected losses.

The terminology and concept of "theoretical yield" appear to be understood and generally used in the pharmaceutical industry. The Commissioner notes that the regulations (e.g., §§ 211.186(b)(7) and 211,192) allow for normal and expected losses before investigations or corrective actions are required. The concept of theoretical yield is important as a basis upon which actual or expected yields can be compared to the theoretical yield to aid in determining acceptance.

80. One comment said the definition of "theoretical yield" is nonspecific in the wording "quantity of components to be used." A suggested alternative wording was "quantity of component specified by master production records for that operation."

The Commissioner sees no need for the suggested revision in the definition section. The requirement for compounding in accordance with master production records is covered elsewhere in these regulations.

81. One comment suggested insertion of the word "distinct" before the word "stage" in paragraphs (b) (17), (18), and (19) of § 210.3 because yields cannot always be determined at any stage of manufacture. Another comment said establishing theoretical yield is not always possible for certain processes involving chemical reactions and production of biologicals.

The Commissioner believes that a theoretical yield can be established for all processes. The theoretical yield for a chemical reaction, for example, would be maximum yield obtainable under optimal reaction conditions. The Commissioner agrees that the word "stage" may not adequately define the phase of manufacture at which the theoretical yield should be determined. Therefore, he is adopting the phrase "appropriate phase" in paragraphs (b) (17), (18), and (19) of § 210.3.

82. A number of comments have been received regarding proposed paragraphs (b) (21), (22), (23), and (24) of § 210.3. As discussed elsewhere in this preamble, the Commissioner is not including in these regulations, at this time, specific requirements regarding "acceptable quality level and unacceptable quality level"; therefore, definitions for these two terms are deleted from the final regulation. Proposed paragraph (b) (21) and (24) is being retained, however, with modifications, as § 210.3(b) (20) and (21).

83. One comment suggested including in the proposed definition of "acceptance criteria" (proposed § 210.3-(b)(21)) the sentence: "Such acceptance criteria may be altered if evidence demonstrates that a valid reason exists for establishing revised acceptance criteria following an appropriate documented quality assurance conference."

The Commissioner notes that the proposed definition, now § 210.3(b)(20), would not preclude a change in product specifications or acceptance criteria if such change is appropriate. There is no need to incorporate the proposed language.

84. One comment suggested elimination of the word "reject" from proposed § 210.3(b)(21), stating that material which is not accepted may be reworked or returned to the supplier.

The Commissioner does not agree with this suggestion. The term "reject" does not denote the ultimate disposition of the product, only that it is not acceptable for use as is.

85. One comment suggested that "sampling plans," referred to in proposed § 210.3(b)(21), are not the only technique used to form a basis for acceptance and rejection.

The Commissioner has used the term "sampling plan" in a broad context here. The term can mean both a plan for collection of physical units for testing, or it can mean a schedule by which an examination of some sort is done.

86. Numerous comments said the term "at random" should be deleted from proposed § 210.3(b)(24). Among the reasons given were that "random" has a limited meaning in statistics, that some samples are best taken on a stratified basis, such as right after each start-up of a run, and that some samples are taken on a timed basis.

The Commissioner is persuaded that the term "at random" without additional clarification may be too limiting for this definition and modifies the final regulation accordingly.

87. In reviewing the proposed regulations, the Commissioner concludes that §§ 211.2 and 211.68 should be combined into a new § 211.68. Proposed § 211.2 is deleted, and the substance of the requirements is included in the new § 211.68. The comments relating to § 211.2 are discussed with those for § 211.68.

88. Three comments were received regarding proposed § 211.3 on definitions for Part 211. Two comments said the section is duplicative and should be deleted. The other comment noted that some of the words defined in referenced § 210.3 are not used in Part 211.

The Commissioner finds that the reference to § 210.3 that appears in § 211.3 is valuable as a cross reference. In addition, he anticipates a need for a definition section in each part of the CGMP regulations to accommodate terms specific to that individual part but not others. This scheme has already been used in the proposed CGMP regulations for Part 212 relating to large volume parenteral (LVP) drug products, published in the FEDERAL REGISTER of June 1, 1976 (41 FR 22202). The Commissioner sees no inconsistency in that terms defined in § 210.3 may not be used in Part 211, because they may be used in other parts (e.g., Parts 225 and 226). The definitions apply only where the term is used.

VIII. ORGANIZATION AND PERSONNEL

89. One comment argued that, as written, the regulations (§§ 211.22-211.34) permit the subordination of the quality control unit's function to any other unit designated by management, including the production unit. Such a subordination of quality control to production was described as a conflict of interest.

The Commissioner do not agree. The CGMP regulations do not subordinate the quality control unit's authority and responsibility to any other unit. At the same time, the regulations regarding the quality control unit does not encroach upon the expertise or responsibility of other units in a firm and do not dictate the organizational structure of a firm. They simply require that the quality control unit have final responsibility for certain actions in the manufacturing process.

90. One comment suggested that CGMP regulations assign individual certification responsibility to persons within the organization. This would include responsibility for review of product specifications and control procedures to assure their adequacy and reliability.

The Commissioner notes that such control responsibilities are already assigned in these regulations to the quality control unit. "Certification" is not specifically required as something more than approval by the quality control unit. Assignment of individual responsibilities within a firm should be left to the discretion of management.

RESPONSIBILITIES OF QUALITY CONTROL UNIT

91. Comments contended that § 211.22, as proposed, would unreasonably interfere with management's right to structure its organization as it deems fit. In addition, it was pointed out that quality control responsibilities are often performed by units of the firm other than the quality control unit; examples cited were formulation designed, development of the manufacturing process, and process control design by research and development scientists, engineers, and other manufacturing specialists. The duties outlined in the proposal for the quality control unit were described as duplicative of functions performed with more expertise in other segments of a firm.

The Commissioner intends to make the quality control unit responsible for ensuring that controls are implemented during manufacturing operations which assure drug product quality, not that the quality control unit actually perform each one of the duties. The Commissioner believes that, even under § 211.22, management has the prerogative to organize its internal structure and assign responsibilities as it deems appropriate, as long as some identifiable person or unit has at least those responsibilities assigned by the regulations to the quality control unit. To clarify that the quality control unit could not and should not perform duties duplicative of other parts of the organization, the Commissioner has modified the definition of "quality control unit" in § 210.3(b)(15). The word "perform" has been deleted and the phrase "be responsible for" substituted. Additional clarification of the Commissioner's position regarding these comments may be found in the preamble discussion under paragraph 78 of this preamble.

92. One comment asked that the responsibilities of the manufacturing units be defined.

As long as provision is made in these regulations for the assignment of certain quality control activities to a quality control unit, the Commissioner believes that other assignments should be at the discretion of individual firms' management.

93. A comment made a distinction between a quality control department and a quality control unit and questioned what duties would be assigned to each. Several other comments suggested that this section dealing with quality control units was primarily designed for large pharmaceutical firms and did not take into consideration that small firms could not comply.

The distinction made between "department" and "unit" is not required by the regulation, which does not specify a name for the quality control

unit, but merely describes several responsibilities that a designated unit must have. The organizational structure of the unit is left up to each individual firm's needs.

A small firm may choose a different means of structuring its organization. The term "quality control unit" is defined in § 210.3(b)(15) as any person or organizational element. This means that in very small operations a single individual can function as the quality control unit. But that person still has the responsibility for implementing all the controls and reviewing the results of manufacturing to assure that drug product quality standards have been met. As discussed above in paragraph 45, the Commissioner rejects the idea that quality control is not needed in a small business.

94. A comment was made that this section precludes the use of outside consulting laboratories for quality control work.

The Commissioner disagrees. There is no such prohibition in the regulations. A manufacturer does have a responsibility, however, to see that the outside laboratory used is qualified to do the work and that the work is performed satisfactorily.

95. With respect to the quality control unit's authority and responsibility under § 211.22(a) for approval and/or rejection of raw materials, in-process materials, and finished products, one person asked that other alternatives be permitted when materials may be suitable for other purposes and uses than those originally intended.

Use of the word "reject" does not necessarily mean that the rejected material must be destroyed. When materials are ordered by a manufacturer, they are ordered with a particular purpose in mind. If testing of a material shows that it is not suitable for a particular use, it may not be used for that purpose and, therefore, is rejected. It may, however, be suitable for other uses requiring a material with differing specifications.

96. Several comments proposed that § 211.22(a) be modified so that the quality control unit would not have to have the responsibility to review all labeling unless it is connected with the manufactured dosage form. The reasoning was that some promotional literature, not physically associated with the drug product, had been defined as labeling in court suits where FDA charged misbranding of a product with promotional literature, but that such material was not labeling in the sense in which these regulations referred to labeling.

The Commissioner notes that the scope of the CGMP regulations is to set forth the facilities, methods, and controls to be used for the manufacture, processing, packing, or holding of a drug product. It is not the purpose of the CGMP regulations to control labeling such as promotional literature that is not associated with the drug product during its preparation under CGMP regulations.

97. Comments asked for modification in the last sentence of § 211.22(a) relating to production of drugs under contract by another company. They suggested that the contractor could release drugs for distribution on his own responsibility if a certificate of analysis showed compliance with appropriate specifications. Others suggested that the responsibility for approving or rejecting drug products produced by contractors appeared in this paragraph to rest with the contractor.

This paragraph clearly says that the quality control unit of a contracting firm must approve or reject drug products produced by contractors. The Commissioner believes this is proper because, in the circumstances described, the contractor does not own the goods, but merely performs a service for the contracting firm. The responsibility to approve release of a drug product for distribution must rest with the owner of the drug product.

98. A number of persons responding to the proposal objected to the example of bioequivalence testing as one of the tests which must be performed in a quality control unit's laboratory. Some said this type of testing was normally done outside the quality control unit, such as by a medical unit. Others complained that bioequivalence standards are in a state of flux and have not as yet been established.

Bioequivalence tests may include tests such as dissolution tests, which are generally done in the quality control unit's laboratory. They also may include in vivo tests done by medical units within or outside the firm. The Commissioner agrees, therefore, that this example is not necessarily one which generally represents the work done in the quality control laboratory. Although he is deleting the bioequivalence testing example, in vitro dissolution tests for bioequivalence are in fact an example of the type of work that could and should be done in the quality control laboratory.

99. Two comments suggested either deleting the reference in § 211.22(b) to "packaging materials" as one of the articles tested in the quality control laboratory, or changing it to "packing materials," on the basis that the examination for suitability of such materials is more properly a function of the shipping department and relates solely to protective qualities to prevent mutilation or breakage of drug product containers.

Breakage of containers can cause product adulteration and mutilation of containers, which may result in product misbranding. The protection of drug products from such mechanical damage is just as much a function of the maintenance of drug product quality as placing light-sensitive products in light-resistant containers or labeling a product with its proper name and an accurate statement of its potency. The Commissioner notes that primary responsibility for selecting specifications for packaging materials may be assigned to the shipping department of a firm. Under § 211.22, the quality control unit is only responsible for testing and approving (or rejecting) packaging materials in accordance with these specifications. Therefore, no change is needed in the section.

100. Several comments proposed eliminating from § 211.22(b) the statement regarding approval (or rejection) of materials used in manufacturing and suggested use of words like "evaluation" or "disposition." It was also suggested by others that "or" be placed between "and" and "approval" to allow for instances described as not requiring testing for approval.

Several discussions appear in this preamble relating to the use of the words "approval" and "rejection." These words mean either that an article may or may not be used for production of a drug product. Reprocessing, reworking, refining, diversion to other acceptable uses, returning to the supplier, or destruction are all actions that may occur after a decision to reject and are in no way precluded by the rejection decision unless specifically stated by the manufacturer.

101. Clarification of the option of using an outside testing laboratory was asked by respondents who wanted an explicit statement in § 211.22(b) of the acceptability of this means of product examination.

The thrust of § 211.22(b) is that adequate laboratory facilities shall be available to the quality control unit from whatever source. The paragraph does not require those facilities to be owned and operated by the drug product manufacturer, nor does it prohibit the manufacturer from using a contract testing facility. The Commissioner does not feel clarification is needed in § 211.22(b).

102. Four comments recommended deletion of § 211.22(c) entirely, because either (1) the requirements are adequately covered in § 211.22(a), or (2) units of a firm other than the quality control unit have greater expertise in specific areas.

The provisions of paragraph § 211.22(a) differ from those of paragraph (c) in that paragraph (a) relates to the actual production of a product, while paragraph (c) covers events which occur before production. The Commissioner realizes that not all ex-

pertise rests with the quality control unit, and he does not believe that the quality control unit should be solely responsible for developing and implementing all procedures and specifications impacting on drug product quality. A manufacturer may assign primary and initial responsibility for selecting procedures or specifications to the persons or units it believes most qualified. The Commissioner's intent is that the quality control unit be responsible for making sure that the procedures and specifications developed are appropriate and followed.

103. One comment indicated that the proposed § 211.22(c) does not allow minor equipment changes that do not bear on drug quality, unless such changes are first approved by the quality control unit.

Section 211.22(c) is limited to those procedures and specifications that impact on drug quality. Moreover, the paragraph does not prevent the production personnel from making minor equipment adjustments that may affect drug quality without the quality control unit's approval of the specific change. It does require that the procedures regarding such equipment adjustment be reviewed in advance by the quality control unit.

104. A comment suggested that § 211.22(c) be expanded to provide for specification committees, formula committees, and others instead of making the quality control unit totally responsible.

As already explained, input into specifications and procedures may come from any appropriate source. If a firm chooses to utilize specification and/or formula committees, it is not prohibited from doing so by these regulations.

105. One firm suggested rewording of § 211.22(d) to eliminate the word "responsibilities" and to add the word "routine" before "procedures." It was suggested that the paragraph as proposed is too broad and that responsibilities for the quality control unit are described elsewhere.

Section 211.22(d) does not define the responsibilities of the quality control unit, but it does require that all its responsibilities, including those required in § 211.22, be in writing. For consistency with other sections in the CGMP regulations, the phrase "such written procedures shall be followed" is being added to § 211.22(d).

PERSONNEL QUALIFICATIONS

106. One comment said § 211.25 is replete with vague terminology, which sets the stage for arbitrary and capricious actions by FDA, thereby placing individuals and companies in a position of unnecessary risk. Two comments stated that this section is one in which FDA attempts to replace management's judgment with regulations.

The Commissioner believes that this section must be of a general and flexible nature to allow management to exercise its prerogatives in light of the various types and sizes of firms, the products made, the differing personnel qualifications needed, the training programs which may be instituted, and other factors. Although such generality will require more judgment to be exercised by FDA investigators who make plant inspections, it does not permit any arbitrary or capricious action by the agency. In addition to the fact that all sanctions authorized by the act may only be enforced through judicial process, FDA is further defining its policy and standards for regulatory action in a series of regulations set forth in 21 CFR Part 7. The Commissioner believes this is ample protection against unreasonable actions by agency personnel.

107. Many comments questioned the frequency of the "continuing training" required in § 211.25(a), asked for a definition of the word "continuing," and questioned who should receive what type of training.

The requirement that training be on a continuing basis is intended to mean, for example, that a single training course at the time an employee is hired, with no subsequent training activities, is not sufficient. Subsequent training should be sufficiently frequent to assure that employees remain familiar with CGMP requirements. The Commissioner does not believe it would be prudent to specify time intervals for training in view of the broad nature of the drug indutry and the wide range of employee functions covered by these regulations. The Commissioner believes this section is sufficiently clear in identifying "who should receive what training" in stating that each person engaged in the manufacture, processing, packing or holding of a drug product must have training in current good manufacturing practice that relates to that person's functions in the firm. The requirements of § 211.25(a) apply to supervisors as well as other employees; § 211.25(b) contains an additional requirement for supervisory personnel.

108. Numerous comments pointed out that paragraphs (a) and (b) of § 211.25 are not consistent in that § 211.25(b), but not paragraph (a), contains the phrase "or any combination thereof" following the phrase "education, training, and experience." Most argued that § 211.25(a) should also contain this phrase.

The intent of the requirement is that a person have a sufficient mix of training, education, and experience to perform his or her job adequately. What is adequate in regard to each of the criteria depends on the job. It may be that a person can adequately perform a particular job with very little or no previous experience, or limited education, or with minimal training, depending on the demands of the job and the qualifications of the person. Because the intent of this section has been misinterpreted, § 211.25(a) is revised to include the phrase "or any combination thereof" and be consistent with paragraph (b).

109. One comment questioned how much education, training, experience, or combination thereof qualifies a person to be a supervisor under § 211.25(b).

The Commissioner believes it should be understood that broad regulations such as these could not reasonably quantify the degree of education, training, and experience necessary. It is left to management's reasonable judgment as to what constitutes sufficient background in these criteria so that supervisors can perform their assigned functions in a manner to provide assurance for the quality of drug products within their purview.

110. One comment on § 211.25 (a) and (b) said it would mean little for some individuals to be instructed in the legal and technical language of the regulations. The respondent indicated that it is more important that personnel be instructed in the principles of good manufacturing practice relevant to their particular tasks.

Section 211.25 requires training in current good manufacturing practice as it relates to an employee's function. The Commissioner intends that training be meaningful to the employee, not a formalistic but useless exercise to satisfy a regulation. The requirement is written to provide reasonable latitude to a firm as to the extent to which technical and legal instruction will be given.

111. A number of comments said the requirement in § 211.25(c) for "an adequate number of personnel" does not belong in the section on personnel qualifications.

The Commissioner notes that the intent of this paragraph in relation to the number of employees is that there be an adequate number of qualified personnel. The Commissioner is revising this paragraph in the final regulation by inserting the word "qualified."

PERSONNEL RESPONSIBILITIES

112. One comment said all persons who enter the manufacturing, processing, packing, and holding areas should comply with the requirements of § 211.28 and the section should reflect this.

The Commissioner agrees that all persons, whether employees or not, who engage in the activities covered by this section should comply with the

requirements of the section. Therefore, the Commissioner is replacing the word "employees" with the word "personnel" in § 211.28 (b) and (d). The Commissioner recognizes that not all persons who enter manufacturing areas are engaged in activities covered by CGMP regulations (e.g., equipment manufacturer service representatives and FDA investigators), and their activities would not be limited by § 211.28. Drug manufacturers are responsible, however, for monitoring such activities to prevent contamination of drug products. For example, all personnel entering a sterile area would be required to wear appropriate protective apparel.

113. One comment said § 211.28 is an additional example of the agency's attempt to legislate and enforce regulations which must be left to the discretion of corporate management in order to preserve our free enterprise system.

The Commissioner does not perceive how these regulations present a threat to the free enterprise system. These regulations were promulgated under the authority of section 501(a)(2)(B) of the act, which was passed by the Congress in 1962 in order to assure that no drug product available to consumers was adulterated. The requirements of the regulations are a reasonable and necessary step toward that goal. They do not inhibit competition, but rather enhance it by assuring that no manufacturer can reduce costs by eliminating those steps integral to the prevention of adulterated products. Thus, the consumer is assured that all marketed drugs meet the essential standards of identity, strength, quality, and purity; and consequently, selection of drugs by the consumer (directly or with the advice of a physician of pharmacist) will be based on fair principles of competition and free enterprise.

114. One comment suggested that in order to make it clear that facial hair coverings should be worn only if necessary, the second sentence of § 211.28(a) should be reworded to read as follows: "They shall wear appropriate head coverings, including facial hair coverings, as necessary to prevent contamination of drug products."

The Commissioner recognizes that clarification of § 211.28(a) is desirable and is therefore revising it to require that protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

115. One comment argued that the meaning of § 211.28(a) is directed to human drug products and should be clarified to limit its scope accordingly.

The Commissioner rejects this comment. These regulations are broad and consider the fact that certain drug products, regardless of whether they are for human or veterinary use, require the same amount of care in manufacturing, processing, packing, or holding in order to assure their safety and effectiveness. The wording of this section requires precautions to be taken as necessary to protect the particular drug products from adulteration or contamination. The degree or types of precautions will depend on the particular drug product being considered.

116. One comment suggested rewording § 211.28(a) by inserting the underlined statement: "Arms and hands shall be covered *or other appropriate measures taken when microbial contamination is a concern* when necessary to protect the drug product being handled"; and that this "appropriate measure" could mean the cleaning of the arms and hands with an antiseptic soap or solution as an alternative.

The Commissioner rejects this alternative wording since it would alter the intent of this paragraph. The possibility of microbial contamination is not the only reason for wearing protective apparel; prevention of particulate contamination, for example, may be of equal importance. Further, the Commissioner does not believe the phrase "as appropriate" would clarify this section since, as written in the final regulation, it clearly states that protective apparel shall be worn as necessary to prevent contamination of the drug product. This paragraph does not preclude other measures such as cleaning which might be used in place of or in conjunction with protective apparel. If alternate methods were at least as effective as protective apparel, then protective apparel would not be necessary.

117. One firm commented on § 211.28(a) that because of its type of operation it does not require, nor does it think it is necessary to have, uniforms if clothing is kept clean.

The Commissioner notes that this paragraph does not necessarily require the wearing of uniforms. The requirement is that clothing be clean enough to be appropriate for the type of duty or operation being performed. For certain types of operations, uniforms may be appropriate, while for other types of operations uniforms may not be necessary.

118. Several comments noted that § 211.28(a) states in part that "they shall wear appropriate head coverings as necessary, including facial head coverings, as necessary * * *." And the comments argued that this statement is "too broad as written since facial hair includes eyelashes, eyebrows, etc."

The Commissioner intended that this paragraph be broad enough to require the covering of eyebrows and eyelashes if necessary to prevent drug product contamination. Although he recognizes that this type of protection would not be usual for most operations, he would not wish to preclude the use of such measures.

119. Several comments argued that, with regard to arm coverings, there are certain kinds of machinery and equipment which present a personal hazard to workers using arm and hand coverings.

The Commissioner recognizes that the use of arm and hand coverings could constitute a significant hazard if used around certain types of machinery. Appropriate alternatives can be used in such instances so that neither personnel safety nor drug product quality is compromised.

120. A comment noted that the term "authorized" in reference to personnel who may enter limited access areas is not defined in § 211.28(c).

The Commissioner believes that drug firms can reasonably determine on an individual basis which personnel should be permitted to enter what areas. The intent of this paragraph is to prevent the type of situation, for example, where persons not trained in aseptic techniques enter aseptic processing areas for reasons not associated with aseptic processing of the drug product. To clarify that the authorization derives from the manufacturer, not FDA, the language of § 211.28(c) is modified slightly.

121. One comment suggested that the word "may" in § 211.28(d) be replaced by the words "is likely to" in order to identify realistically the threat of illness or lesions.

The Commissioner rejects this alternative wording because the phrase "is likely to" is not strong enough to state the intent of this paragraph. Further, the alternative phrase would introduce the element of prediagnosis by the employee's supervisor. While supervisory personnel can reasonably be expected to recognize health conditions that may affect the drug product, they probably would not be able to recognize conditions that are likely to affect the drug product. This may require more sophisticated evaluation by medical personnel. Of course, if medical personnel determine that the employee's health condition will not affect the drug product, the employee may resume his or her routine activities.

122. One comment argued that the words "they consider" be deleted from the last sentence of § 211.28(d) because the reporting of conditions should not be limited to conditions which an employee thinks may affect the product. Another comment said the word "health" should be inserted between the words "any" and "conditions" in this sentence.

The Commissioner agrees that the intent of this paragraph is better served without the phrase "they consider" and with the addition of the word "health" and has revised the final regulation accordingly.

123. Several comments said § 211.28(d) should not be construed to imply that supervisors are medically qualified to judge health conditions of employees.

The Commissioner does not believe the paragraph implies this. Within the framework of industrial management, the supervisor is the liaison between the operating employee and higher echelons of the company. It is the supervisor who is most likely, on a day-to-day basis, to notice health conditions that may affect the drug product. Of course any such conditions noted initially by the supervisor may require evaluation by qualified medical personnel. Such medical evaluation is acknowledged in the final regulation. This section could perhaps set out more detailed procedures for dealing with employee health problems. But in the absence of significant difficulties in the area, the methods for dealing with health problems, beyond the initial phase of removing suspect employees from direct contact with drug products and their components, are left to the reasonable judgment of individual firms.

CONSULTANTS

124. Several comments were received requesting deletion of § 211.34 because the ultimate liability for actions taken based on the advice of consultants still rests with the responsible officials of the drug product manufacturer. The argument is that a firm's choice of consultants should be a matter of its own judgment and not one of Government review or regulation. The comments also state that FDA lacks authority under the act to prescribe qualifications for consultants.

The Commissioner considers that consultants, while they are retained by the firm, are persons engaged in the manufacture, processing, packing, or holding of a drug product, and may lawfully be subjected to appropriate standards of qualification to the same extent as full-time employees of the firm. Therefore, consultants must have education, training, and experience, or any combination thereof, sufficient to perform their assigned functions. Minor editorial amendments have been adopted in the final regulation to clarify this requirement.

125. Several comments requested that § 211.34 state that the requirements are applicable only to consultants who are retained for activities that relate to the scope of the CGMP regulations.

The Commissioner acknowledges that activities that are not under the scope of the CGMP regulations should not be subject to such requirements. The final regulations are clear in this regard.

126. One comment asked that the term "consultant" be better defined in § 211.34 to clarify, for example, whether the term "consultant" includes attorneys. It also asked if firms will have to document the qualifications of outside counsel.

Under these regulations, a consultant is a person from outside the firm who is called on to render advice or opinion on current good manufacturing practice as it relates to the facilities or controls to be used in the manufacture, processing, packing, or holding of drug products. The Commissioner believes this is generally well understood in the industry and sees no need to define "consultant" in these regulations. Any person, including attorneys, employed or retained to advise on the manufacture, processing, packing or holding of drug products would be considered a consultant under these regulations. However, an attorney employed or retained for legal advice—for example, an interpretation of CGMP regulations—would not be considered a consultant under these regulations. In response to the second part of the comment, the section requires that records be maintained stating the name, address, and qualifications of any consultant used.

IX. Buildings and Facilities

DESIGN AND CONSTRUCTION FEATURES

127. A number of comments suggested that the last sentence of § 211.42(b), which deals with unnecessary traffic, is ambiguous. Two comments contend that the phrase "particularly movement back through areas in which these materials had previously been processed or held" be deleted as superfluous.

The Commissioner is revising this paragraph to clarify the intended requirement that the flow of materials shall be designed to prevent contamination.

128. One comment proposed that under § 211.42(c) the paragraph be divided into those operations which must be in defined areas and those which must be in separate areas. A number of comments regarding this section and § 211.89 objected to a requirement that areas be set aside exclusively for quarantine storage.

The intent of this paragraph is to require that enough physical separation be employed as is necessary to prevent contamination or mixups. The degree of separation will depend on the type of operation and its proximity to other operations within the plant. The phrase "separate or defined" is not intended necessarily to mean a separate room or partitioned area, if other controls are adequate to prevent mixups and contamination. In the case of quarantined areas, for example, an effective means of identifying the quarantined goods and a paper control or other system may be used in lieu of complete physical separation. Thus, the regulations do not requrie that space be reserved for quarantine storage. The Commissioner believes, however, that some degree of separation, even though only spatial, would be necessary in most cases, even with elaborate supplemental control.

129. One comment maintained that the quarantine of containers and closures involves a great deal of space which most small manufacturers do not have. The comment further contended that these items "can be examined at the packaging line just before use" or "can be examined at the distributor's facilities before shipment."

If suitable specifications for containers and closures are simple enough to permit a quick visual examination to determine the product's acceptability, such an examination could be performed at the time of receipt without being in conflict with the quarantine requirements of these regulations. A certificate of testing received from a supplier would not preclude the necessity for examining containers and closures to determine that they are the same articles as are represented by the certificate. Any manufacturer who does not have such evidence of an article's acceptability or does not alternatively quarantine the article until such evidence is obtained is assuming an unacceptable risk that the article will be used and subsequently be found unsuitable.

130. A number of comments indicated that the requirement in § 211.42(c) that "operations shall be performed in specifically defined areas of adequate size" was unnecessarily restrictive on the flexibility of plant space use.

The requirement relates to several different types of operations which are enumerated in the proposal; however, the comments seemed to relate mainly to storage areas. It is the Commissioner's belief that a significant type of control over products is a physical one which precludes mixups by physically placing an article in an area clearly identified as to status. The extent of the physical separation imposed in a particular situation can vary from locked, walled-off areas to simple designation of an area for a single purpose by means of a sign. The degree of physical control will vary depending on the other controls in use by a firm. If a firm has effective controls, whatever they may be, that would increase their confidence that mixups will not occur, then the degree

of physical control may be less than in another firm where no other controls exist.

131. One comment contended that § 211.42(c)(2) would require availability of a large separate holding area in the warehouse for relocation of rejected supplies.

The Commissioner concludes that preventing the intermingling of rejected supplies with released supplies is very important to drug quality. The regulation does not require separate facilities as long as there is a defined area for rejected materials. The Commissioner is not aware of any problems in the past with regard to large numbers of rejected supplies and their storage. He therefore rejects the proposal.

132. One comment objects to the requirement in § 211.42(c)(4) for separate storage for "in-process" materials and suggests adding to this paragraph the words "if storage or isolation is necessary."

The use of the word "storage" in this paragraph implies holding for extended periods of time. It does not refer to the holding of containers in production areas while processing is ongoing. Therefore, if such storage is not necessary, the regulation as currently written is inapplicable. On the other hand, if such storage is necessary, it is the Commissioner's opinion that isolation in a separate or defined area is essential to prevent errors. Therefore, the comment's proposal is not accepted.

133. One comment, referring to § 211.42(c)(5) said "on-line testing does not have to be done in a separate testing area * * *."

The requirement is for separate or defined areas. The Commissioner believes that the area in which testing occurs, including on-line testing, must be defined or separated in order to prevent contamination of on-line products with testing materials and improper use of products that have been tainted by the testing process.

134. One comment requested that § 211.42(c)(5) be deleted since it is too broad to be helpful.

The Commissioner disagrees with this comment. The intent of this paragraph is to avoid mixups by using defined areas for the entire manufacturing operation, phase-by-phase. The detailed procedures are purposely not spelled out so that pharmaceutical manufacturers can design their operations according to their individual needs.

135. Two comments argued that the word "quarantine" in § 211.42(c)(7) is not defined, the word means different things to different people, and it should be deleted.

The word "quarantine" has had widespread use in the pharmaceutical industry, and its meaning is well understood. These regulations do, however, have the effect of defining the word within the context of the pharmaceutical operations by indicating that it constitutes a control system to prevent unauthorized usage of unreleased material. The Commissioner does not believe further definition is necessary.

136. One comment argued that § 211.42(c)(7) "increases warehouse requirements. This is not believed to be current practice in industry."

Based on experience gained from FDA inspections of drug manufacturers, the Commissioner believes that most firms now separate released and unreleased drug products. In view of the intent of the phrase "separate or defined" as explained elsewhere in this preamble, the Commissioner concludes that § 211.42(c)(7) and, similarly, § 211.42(c)(8) reflect current industry practice and will not increase warehouse requirements.

137. A number of comments indicated that all the controls listed under § 211.42(c)(10) are not needed in aseptic processing areas for every product or process. One comment suggested that the term "aseptic processing" in § 211.42(c)(10) requires further clarification to indicate that such processing is intended for products or components which are not terminally sterilized. The respondents suggested inserting a phrase which would make it clear that not all controls are necessarily required.

It is not the intent of § 211.42(c)(10) to require "aseptic processing" when such operations would not be necessary for the firm's usual activities. Some firms choose to use aseptic processing for drug products not intended to be marketed as "sterile" as a means of controlling microbial contamination. The Commissioner agrees that modification is desirable and is revising § 211.42(c)(10) to include the words "as appropriate."

138. One comment suggested that § 211.42(c)(10) should be redesignated as paragraph (d) because it is unrelated to paragraph (c).

These requirements relate to separate or defined areas for certain operations to prevent product contamination or mixups. The Commissioner concludes that such requirements are appropriately codified.

139. Several comments objected to the requirement under § 211.42(c)(10)(i) that floors, walls, and ceilings have smooth, hard surfaces.

The Commissioner rejects these comments. It is widely acknowledged that smooth, hard surfaces are easier to clean and sanitize.

140. A number of comments objected to applying the requirements of §§ 121.42(d), 211.46(e), and 211.176 to the manufacture of penicillin and nonpenicillin veterinary products. They claim that no evidence has been offered to demonstrate penicillin sensitivity in animals. It was proposed that the word "human" be inserted before the words "drug products."

Hypersensitivity reactions to penicillin do occur in animals. Although the Commissioner acknowledges that at present there is less information on the extent of the problem in animals than in humans, he advises that FDA has received numerous reports of reactions in animals throughout the years. Therefore, the Commissioner believes the requirement as proposed in § 211.176 is warranted and has retained it in the final regulation. However, the Commissioner believes that the prohibition against the use of common facilities and air-handling systems in the production of veterinary drug products is not necessary at this time. Therefore, §§ 211.42(d) and 211.46(e) (now 211.46(d)) are revised accordingly in the final regulation.

141. A number of comments suggested that § 211.42(d) can be too broadly construed. It was suggested that some processing steps for penicillin and nonpenicillin products could be performed on the same equipment without risk of cross-contamination.

The Commissioner believes that there is a possibility of trace amounts of penicillin being released during product handling even under well-controlled conditions, and he therefore cannot accept this suggestion.

142. Another comment requested clarification of the meaning of the word "separate" in § 211.42(d).

The Commissioner's intent in this paragraph is to require the isolation of penicillin production operations from operations for nonpenicillin products. Separation can be achieved in a facility, building, or plant by effectively isolating and sealing off from one another these two types of operations. This does not necessarily mean separation by geographical distance or the placement of these operations in separate buildings. Effective means can almost certainly be developed to separate such activities from one another to prevent cross-contamination problems within a single building. An example of the means of separation can be found in the discussion of air-handling systems in this preamble under paragraph 172.

LIGHTING

143. Two comments said § 211.44 is vague and may lead to misinterpretation.

It is not the intent of this section to spell out precisely what is required in the way of lighting for each type of operation, but rather to require that individual firms follow lighting stand-

ards that are generally considered adequate for each of their various operations. For example, inspection of parenteral solutions for particulate matter requires a different type of illumination than a component storage area. The Commissioner, therefore, has retained the proposed wording in the final regulation.

VENTILATION, AIR FILTRATION, AIR HEATING, AND COOLING

144. One comment suggested that the word "microorganisms" in § 211.46(b) be modified by the term "objectionable."

The Commisioner finds that this paragraph, by use of the phrases "adequate control" and "when appropriate," adequately states that the number or types of microorganisms that would be undesirable must be controlled. Therefore, the Commissioner has retained the wording as proposed in the final regulation.

145. A number of comments requested that expressions such as "when necessary," "where applicable," or "where appropriate" be used in the first sentence of § 211.46(c) to broaden the scope of the requirement for air filtration systems. Comments took exception to the requirement for exhausting to the outside of the building, stating that there are a number of alternatives such as completely closed systems properly filtered, ionization and electrostatic precipitation, enclosed hoods, and scrubbers. Finally, two comments contended that there is no reason for air filtration systems in production areas where the product is already in the final sealed container and in nonsterile processing areas.

The Commissioner believes that for the great majority of drug production operations the proposed requirement is desirable and necessary to assure the quality of drug products. While it is doubtful that such air systems are not generally applicable to the production of nonsterile products, there may be situations where the requirement would not be necessary to assure the quality of drug products and would therefore be unreasonable. Therefore, § 211.46(c) is revised in the final regulation to require such filtration systems where appropriate. This paragraph as rewritten also allows alternative systems which do not necessarily exhaust outside the building.

146. Several comments objected to proposed § 211.46(d) on the grounds that effective exhaust systems need not always be "adjacent" to the equipment in dusty operations.

The Commissioner concludes that proposed § 211.46(d) is unnecessary in view of § 211.46(c) as written in the final regulation. Therefore, proposed § 211.46(d) is deleted in its entirety.

147. One comment said proposed § 211.46(e) (now § 211.46(d)) is too general because there would be no danger from cross-contamination during penicillin fermentation (prior to processing the dry state) and after the sealing of the product.

The Commissioner cannot agree with this comment since the operations specified are not clearly defined. He believes the fermentation process could result in cross-contamination problems. For example, removal of the cake from penicillin fermentation equipment could result in airborne contamination from partly dry or dry cake. With regard to the respondent's second example, the Commissioner is revising this requirement to make it apply only to production operations and not to storage, such as warehousing of the penicillin product in sealed containers.

148. Comments were made that proposed § 211.46(e) was superfluous because § 211.42(d) already required separate facilities for penicillin and nonpenicillin products.

The Commissioner believes it is important to make clear in these regulations that completely separate air-handling facilities for penicillin and nonpenicillin production are required. Section 211.42(d) is written to allow penicillin production in the same buildings as nonpenicillin production if the penicillin production areas can be completely separated from all others. However, because it is possible for air-handling systems between penicillin and nonpenicillin production areas to be interconnected, the Commissioner finds it necessary to state that any such interconnection would be unacceptable.

149. One comment said proposed § 211.46(e) should specify whether the air-handling system is intended for outgoing or incoming air.

There is no single answer to this point since the specific requirements for a particular installation will depend on individual circumstances. The purpose of the requirement is that no cross-contamination occur between penicillin and nonpenicillin operations. The means by which the objective is achieved may require filtration of incoming air of filtration of outgoing air or both.

PLUMBING

150. A number of comments on § 211.48(a) said water received from municipal sources and certified as meeting the requirements of Subpart J of 42 CFR Part 72 should not have to be tested as if it were another component.

It was not the Commissioner's intent that potable water received from municipal sources require acceptance testing by a drug manufacturer unless the water is obtained from sources that do not control the water quality to assure compliance with Public Health Service standards. Of course, water of unknown quality such as a firm's own wells must be tested, and potable water coming into the plant system should not be adversely affected by the in-plant plumbing.

151. A number of comments indicated that it is not necessary and is very expensive to require that all water in a plant be potable water. They pointed out that some systems such as sprinklers for fire control, cooling equipment, and boiler feed do not require potable water.

In light of these comments, the Commissioner is revising § 211.48(a) to eliminate the prohibition against nonpotable water within a plant.

152. One comment said potable water should be analyzed for polychlorinated biphenyls and chloroform, and tolerances should be set because of the potential danger to health represented by these contaminants.

The Commissioner recognizes that potable water may contain amounts of environmental chemical contaminants at levels that have not been clearly established as having significant adverse effects when ingested. Government agencies are investigating more meaningful specifications for testing potable water for potentially harmful impurities not already included in the standards. Therefore, FDA has not included such requirements for testing and acceptance of potable water in these regulations.

153. Several comments objected to the designation of traps to prevent back-siphonage in § 211.48(b). The comments said it is general opinion that traps do not prevent back-siphonage, but check valves or air break arrangements would do so.

The Commissioner agrees with these comments, and § 211.48(b) is revised to reflect the suggested change.

154. One comment objected to equipping drains with traps because of the inflationary impact and requested that this paragraph be deleted.

The Commissioner notes that this paragraph is revised to eliminate the reference to traps. It now requires the use of air breaks or other mechanical device which may increase or decrease the cost to this person, depending on his present method of preventing back-siphonage. However, the Commissioner considers that the necessity of preventing back-siphonage outweighs the cost factor.

WASHING AND TOILET FACILITIES

155. Several comments on § 211.52 argued that it is not current industry practice to provide "hot" water, but rather to provide "tempered" water,

thus conserving energy while maintaining adequate sanitation facilities.

The Commissioner has been unable determine that there is a consensus as to what is meant by "tempered water." Therefore, he is concerned that the word "tempered" might allow the use of water that is of insufficient temperature for adequate cleaning.

156. A comment suggested that the word "easily" be deleted from § 211.52 because location of washing facilities may be hindered or prohibited by local plumbing codes. Further comment said the word "easily" is most subjective and capable of differing interpretation.

The Commissioner is not convinced that plumbing codes would prohibit easily accessible washing facilities in establishments that are properly designed. Further, the Commissioner believes that the word "easily" is concise enough to adequately describe the intent of the section. Therefore, the wording as proposed is retained in the final regulation.

ANIMAL FACILITIES

157. Several comments contended that proposed § 211.54 should be deleted since it substance is covered by the Animal Welfare Act of 1970 (Pub. L. 91-579, 7 U.S.C. 2131). Other comments said this section implies that housing for laboratory animals is required whether or not a firm maintains laboratory animals.

The Commissioner does not believe it is improper to make the substance of another regulation a requirement in th CGMP regulations. It should be obvious that if a firm is not engaged in a type of operation covered by these regulations, then any requirement that pertains to that type of operation does not apply to that firm. In reviewing this proposed section, however, the Commissioner has concluded that its intent is adequately covered in § 211.173. Therefore, § 211.54 is deleted in the final regulation.

SANITATION

158. Several comments on § 211.56(a) said it is impossible to maintain all buildings completely free from rodents, birds, insects, vermin, trash, and organic decaying matter. In most buildings there is an accumulation of trash daily in various waste baskets and in trash accumulation areas for papers and empty cartons.

The Commissioner agrees that the intent of this section could be more clearly stated, and the text is revised accordingly.

159. Several comments requested the deletion of the phrase "in detail" from § 211.56(b) because, according to the language in this paragraph, manfacturers would be required to document all minute details.

The Commissioner believes that in some cases, detailed descriptions of cleaning procedures may be necessary to assure complete and proper cleaning. In others, that level of detail may not be necessary or appropriate. The Commissioner believes that there should be a reasonable standard in describing the details of these procedures. Therefore, this paragraph is revised to require "sufficient" detail.

160. Several comments requested the deletion of the phrase "such written procedures shall be followed" from § 211.56(b) because, if current good manufacturing practice involves writing down certain procedures, it also involves following them.

The Commissioner does not agree with this comment. Procedures may be written with obvious good intentions but never implemented, as the agency has discovered in some firms. Written procedures must be followed to assure the quality of finished drug product, and the regulations should be explicit in stating this point.

161. Comments regarding § 211.56(c) objected to the use of the word "person" and to the requirement of "evidence" that use of such materials will not contaminate equipment, components, or in-process materials. the use of the word "person" according to the comments seems to have a more personal use here than the general use it has in other sections. It was also suggested that the word "evidence" implied a need for proof of lack of any residue from pesticide or cleaning agent use, and that the standard should be a lack of adverse effect instead. Several comments suggested that as written, this paragraph would require residue checks to be run on all batches in an area after a visit by an exterminator.

The Commissioner finds that the objections have merit, and therefore the opening of this paragraph is reworded to clarify the intent. It is not the intent of the Commissioner to burden manufacturers with testing every batch of drug product in a particular area for contamination from chemicals used to kill pests and insects.

162. Several comments requested the deletion of the last sentence of § 211.56(c), which allows the use of only those rodenticides, insecticides, and fungicides that have been registered in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135).

The Commissioner believes it contrary to public policy to permit the use of unregistered rodenticides, insecticides, or fungicides. The comment is rejected.

163. One comment requested insertion of the phrase "employed to perform sanitation work" following the word "employees" in § 211.56(d) to clarify that the procedures apply to individuals who are assigned to sanitation work.

The Commissioner believes that the paragraph clearly indicates that good sanitation procedures apply to all employees who perform sanitation work. Therefore, he rejects this comment.

MAINTENANCE

164. Several comments said the phrase "good state of repair" in § 211.58 is vague and is subject to varying interpretation.

The Commissioner does not agree that the phrase "good state of repair" is vague. It means that buildings should not be in a bad state of repair so that drug products processed within them are adversely affected.

X. EQUIPMENT

EQUIPMENT DESIGN, SIZE AND LOCATION

165. A comment suggested the deletion of the phrase in § 211.63 "for its intended use as well as for its" on the grounds that it is redundant and therefore unnecessary.

The Commissioner does not agree that this phrase is redundant. The regulation imposes two requirements: that equipment be such as to facilitate its operations for its intended use and that equipment be such as to facilitate its cleaning and maintenance. The phrase is revised in the final regulations for clarity.

166. One comment on § 211.63 noted that medical gas manufacturers use dedicated piping systems, manifold valve outlets, and pin index systems for processing medical gases. Cleaning, except at the time of initial installation and subsequent maintenance, is not done internally.

The Commissioner notes that this section does not dictate the frequency of cleaning and/or maintenance. If cleaning and maintenance after initial installation are not needed, as stated in the comment, then there is no requirement in § 211.63 for such practice.

EQUIPMENT CONSTRUCTION

167. A number of comments argued that § 211.65(a) literally requires that all product contact surfaces be totally inert. The respondents maintained that this requirement is practically impossible to achieve and that the following wording should be added: "* * * so as to alter the safety, identity, strength, quality or purity of the drug beyond the official or other established requirements."

The Commissioner recognizes that drug product contact surfaces may be reactive to some minute extent, and the paragraph is revised in the final regulation in accordance with suggested alternative wording.

168. A number of comment suggested adding the phrase "beyond the official or other established requirements" to the end of § 211.65(b) to define better the standards to be used for evaluating any possible changes caused by product contacts.

The Commissioner agrees with the substance of these comments. The proposed phrase is added at the end of the sentence in § 211.65(b) for the same reason as explained in reference to § 211.65(a). A similar change is made in § 211.67(a).

EQUIPMENT CLEANING AND MAINTENANCE

169. In reviewing the proposed regulations the Commissioner concludes that §§ 211.67 and 211.112 should be combined into a new § 211.67. Section 211.112 is deleted from the final regulation, and the substance of the requirements in proposed § 211.112 are included in the new § 211.67. The comments below include those relating to both proposed §§ 211.67 and 211.112.

170. Several comments said written procedures and documentation required by § 211.67 should apply only to major equipment, not to items such as ladles, buckets, and spatulas.

The Commissioner does not necessarily intend to require detailed procedures for cleaning each type of utensil. For example, such equipment may be grouped when convenient. However, the Commissioner believes that at least general written procedures should be instituted for cleaning utensils. Although not "major" pieces of equipment, utensils can be just as much a source of contamination. Depending on the type of operation, it may be necessary, for example, to sanitize or use procedures other than simple washing.

171. One comment said § 211.67 should be strengthened by requiring that cleaning and identification be performed by a competent individual specifically trained for these operations.

The Commissioner rejects this comment because it would be repetitive of the requirements in § 211.25 on personnel qualifications.

172. One comment on § 211.67(a) said that when equipment is dedicated to a single component or product, the use of water solution or gas purging would serve only to introduce material which should not be in the final product.

This paragraph does not prescribe what compounds must be used for cleaning, the manner, or the exact frequency of cleaning. To do so would be impossible, given the variety of products, equipment, manufacturing operations, and cleaning techniques. Selection is best left to each manufacturer, who also retains responsibility for assuring that their cleaning operations do not contaminate the drug product.

173. One comment said the list of procedural requirements for equipment cleaning should be deleted from § 211.112(a) since it is unnecessarily specific and unduly restrictive.

The Commissioner does not agree that the list of required procedures is either too restrictive or too specific. He believes that all the items are common sense procedures that most firms would incorporate, but some would not in the absence of CGMP regulations.

174. One comment on proposed § 211.112 argued that the word "shall" in the sentence regarding establishment of procedures should be replaced by the word "may" because the judgment of the manufacturing personnel should determine proper sanitary procedures.

The Commissioner rejects this suggestion. The purpose of these regulations is to assure that each firm establish appropriate written procedures regarding sanitation. Precise procedures are left to the reasonable judgment of manufacturing personnel, as long as the objectives of the requirement are met.

175. One comment said that § 211.67 as written requires the cleaning and maintenance of all equipment used in the manufacture, processing, packing, and holding of a drug product, which would include laboratory equipment, fork lifts, and truck fleets.

Any equipment used in association with drug manufacturing that could have an adverse effect on drug product quality if improperly maintained is covered by this section. Ordinarily, of course, fork lifts and fleet trucks would not be considered, but it is not inconceivable, for example, that the failure of a refrigeration unit in a truck could have a serious deleterious effect on drug products that must be kept cool. Laboratory equipment, when used for the quality control of drug products, is an integral part of the manufacture, processing, packing, or holding of drug products and therefore clearly is included in the scope of § 211.67.

176. Several comments on § 211.67 argued that requiring written procedures for the method used in the disassembling and reassembling of all equipment is overly burdensome and not necessary. It was recommended that the paragraph be deleted or rewritten to require such measures for significant pieces of equipment only. It was also recommended that parts which come into contact with drug products be disassembled, cleaned and reassembled, but not necessarily the entire piece of equipment.

The Commissioner concludes that the extent to which equipment must be disassembled depends on the type of equipment and other variable factors. The equipment must be disassembled to the extent necessary to prevent subsequent contamination and/or malfunction. The regulations in § 211.67(b)(3) are clarified in this regard.

177. Several comments said § 211.67(b) would require written procedures for "maintenance" of equipment and objected that the word "maintenance" is too general a term. One comment recommended that the paragraph be revised to read, "There shall be written procedures assigning responsibility for and describing preventive maintenance programs and cleaning schedules."

The Commissioner does not agree that rewording the paragraph, as suggested, is necessary. Maintenance means keeping a building, machinery, or other facilities in a good state of repair; and the term is understood throughout the industry.

178. One comment said § 211.67(b) is not relevant to good manufacturing practice for most products. The comment further said the description of the methods of disassembling, cleaning, and sterilizing is applicable only to parenteral drugs.

The Commissioner does not agree with this comment. Other types of equipment, for example, automatic tableting machines, also require disassembling, cleaning, and reassembling.

179. Several comments requested that the phrase "such written procedures shall be followed" be deleted from § 211.67(b).

The Commissioner does not agree with this comment. The requirement for written procedures is only part of the requirement for the use of current good manufacturing practice in the production of drugs. An equally critical part of the requirement is that the written procedures be followed.

180. One comment objected to the requirement in § 211.67(c) for making the maintenance and cleaning records a part of the equipment use log (as required in § 211.182) because the information is readily available in batch records.

The Commissioner rejects this comment. The intent of the record retention requirement is that cleaning and maintenance records be readily identifiable with equipment usage in the event of a problem where drug products must be investigated. Where the same equipment is used for a number of different drug products, for example, cleaning and maintenance records may not be easily retrieved. Section 211.182 in the final regulations provides, however, that individual equipment logs are not required where equipment is dedicated to the manufacture of one product and the batches are manufactured in numerical sequence.

181. Several comments requested the deletion from proposed § 211.67(c) and § 211.112(a)(6) of the references to §§ 211.180 and 211.182 with regard to the record retention period.

The Commissioner disagrees with these comments. Section 211.182 provides the specific information and form in which equipment usage, cleaning, and maintenance records must be kept and is appropriate so that firms subject to these regulations are made aware of their responsibilities.

Further, improper cleaning and sanitizing could contribute as significantly to adulteration of products as could other problems in the manufacturing process and, in the event of contaminated products, the firm should be able to identify the cause of the contamination. The retention of these records under § 211.180 therefore should be consistent with other recordkeeping requirements throughout the CGMP regulations.

EQUIPMENT CALIBRATION

182. The Commissioner is combining the substantive requirements of proposed §§ 211.2 and 211.68 to form new § 211.68. Comments on proposed §§ 211.2 and 211.68 will be discussed here.

183. One comment requested that proposed § 211.2(a) be modified to permit the use of equipment other than the types listed. One comment argued that the use of computers should be allowed. Several comments suggested deletion of the word "precision" since it is superfluous and redundant.

The intent of this paragraph is to allow the use of any equipment that will perform a function satisfactorily in accordance with the requirements in Part 211. The Commissioner is therefore revising this paragraph in the final regulation (now § 211.68(a)) to permit the use of any automatic, mechanical, electronic, or other types of equipment, including computers or related systems, that will achieve this goal. Use of modifying word "precision" is not necessary because the paragraph requires that any equipment perform a function satisfactorily.

184. One comment suggested that the word "permit" in § 211.2(a) be replaced by the word "recognize," which would better express the intent of the paragraph. Several comments questioned the statutory authority of FDA to permit or prohibit the use of specific types or classes of equipment.

The revision of proposed § 211.2(a) (now § 211.68(a)) eliminates the word "permit." The authority to promulgate CGMP regulations includes the authority to regulate the use of equipment that could have a bearing on drug product quality. The argument that FDA does not have the authority to prohibit the use of equipment is academic, however, because there is no prohibition stated or implied. Testing and quality control are an inherent part of the manufacture, processing, packaging, and holding of drug products as defined in § 210.3(b)(12). Therefore, such equipment may also be used for testing and quality control.

185. Numerous comments suggested that the requirement in proposed § 211.2(b) for a backup file of hard copy data be amended to provide for other types of backup data, such as duplicate tapes or microfilm.

The Commissioner is convinced that it would be proper to allow for backup systems other than hard copy, and this paragraph is revised accordingly as § 211.68(b). Measures must be taken, however, to assure that backup data are exact and complete and that they are secure from alteration, inadvertent erasure, and loss.

186. Several comments objected to the requirement in proposed § 211.2(b) for checking computer reproductions of formulas and other records or data each time they are used, on the grounds that it should be sufficient to verify only the accuracy of the first reproduction.

The intent of this requirement is to ensure that each reproduction is the same as the original. Computer printouts do, on occasion, contain errors. Whether due to faulty input, programming, malfunction, or other reasons, they can result in a serious production error and the distribution of an adulterated product. The Commissioner therefore does not agree that only the first reproduction need be checked for accuracy. If a computer system has the capability, however, to verify its output, such as with audit trials, this could be considered as a check for accuracy.

187. One comment suggested deletion from proposed § 211.2(b) of the listing of items requiring backup data.

The Commissioner now believes that the listing of data to be included as hard copy data is not necessary. The intent of this paragraph is that backup data be kept of any information that is computerized, not that certain information be computerized.

188. One comment suggested deletion of the word "appropriate" in the second sentence of proposed § 211.2(b), charging it to be superfluous.

The Commissioner rejects this suggestion. Controls required by this paragraph must be adequate to achieve their purpose, but are not required to exceed this level.

189. One comment suggested that the third sentence of proposed § 211.2(b) be modified by deleting the word "reproductions" and replacing it with the phrase "input to the computer." The comment also suggested deletion of the phrase "data from the computer."

The Commissioner agrees that input to the computer must be checked for accuracy and is revising the paragraph accordingly in § 211.68(b). He does not agree that "data from the computer" need not be checked for accuracy and therefore rejects that portion of the comment. In considering the comments on the section and as a result of discussions with FDA staff knowledgeable in the computer field, the Commissioner has become aware that use of the word "computer" may be too restrictive so as to exclude data processing systems that do not compute. Therefore, the words "related systems" are added to include those systems that function only as data storage and retrieval.

190. One comment on § 211.68(a) asked whether electronic equipment recorders should be calibrated.

The Commissioner believes that recorders are an integral part of precision equipment systems. A faulty recorder may give unreliable results that may affect the quality of finished drug products. Recorders that are routinely calibrated, inspected, and checked reduce the margin for error and assure the quality of drug products.

191. A comment said the intent of § 211.68(a) is not clear as to the use and type of equipment that is applicable. The comment further said precision equipment that has no effect on the drug product quality should be exempted from the written program requirements.

The paragraph refers to equipment which is used in the manufacture, processing, packing, and holding of drugs and may therefore have an effect on drug product quality. No examples of equipment which did not have an effect on drug product quality were offered.

192. A comment requested that the term "precision automatic equipment" be defined. The respondent said it could, for example, include tablet counters and liquid fillers which are checked on a routine in-process basis where there is no need for routine calibration or inspection.

The Commissioner believes that tablet counters and liquid fillers are examples of precision automatic equipment. When routing in-process checks are made, regardless of the time interval, such checks should be performed according to prescribed procedures and records kept in accordance with the requirements of this paragraph.

193. Several comments on § 211.68(b) said the mandatory time interval of 6 months for calibration checks on scales and balances is arbitrary.

The Commissioner agrees that time intervals longer than 6 months may be appropriate in some cases. Because § 211.68(a) requires that automatic, mechanical, and electronic equipment, including scales and balances, be calibrated routinely to assure the quality of drug products, the provisions of § 211.68(b) are unnecessary and therefore are deleted.

193a. A comment requested the insertion of the word "weight" before the word "scales" in § 211.68(b) to clarify that this requirement applies only to weight scales.

The deletion of § 211.68(b), as proposed, removes the reference to "weight"; however, the Commissioner finds that any scale or balance used for testing of production operations is required to be accurate and must be calibrated and checked routinely as required in § 211.68(a).

194. A comment requested an additional paragraph covering the standardization of tablet punch and die sets.

Although the Commissioner believes that the comment has merit, he does not believe that it is generally appropriate in a general set of regulations to identify specific equipment used only in the manufacturing of one dosage form. Such requirements are more appropriate in regulations for specific dosage forms.

FILTERS

195. A number of comments on § 211.72 requested clarification whether this section is intended to apply to both air filters and solution filters. Other comments requested clarification that the proposed paragraphs (b) and (c) refer only to injectable drug products intended for human use.

The Commissioner finds that the intent of this section is to eliminate the use of fiber-releasing filters in liquid filtration systems during production of injectable drug products for human use. Revisions appearing in the final regulation clarify this intent. Additional background information regarding this requirement can be found in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865), which established the basic requirements for this section.

196. Several comments suggested that this section be deleted because it pertains only to injectable drug products and therefore should be placed in the specific regulations for this type of drug product.

The Commissioner agrees that this section and a portion of § 211.94 apply only to injectable drug products for human use and that such requirements will be suitable for the more specific regulations for large and small volume parenterals for human use when such regulations are in effect. The Commissioner previously concluded in the final regulation published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865) that the use of fiber-releasing filters in the production of human injectables required codification in the general CGMP regulations until final LVP and SVP CGMP regulations are codified. These provisions will be incorporated in the more specific regulations regarding human parenteral drug products when they are published as final regulations. Again, the Commissioner reminds interested persons that this section has been in effect since April 14, 1975 (40 FR 11865).

197. One comment noted that by the time the final regulation becomes effective, proposed § 211.72(c) will be inoperative, since it requires substitution on or before September 14, 1976.

The Commissioner agrees with this comment and is therefore deleting paragraph (c) of § 211.72.

198. One comment objected to being forced to use filters in drug production.

Section 211.72 does not require the use of filters in the manufacture, processing, or packing of injectable drug products. However, if filters are used, § 211.72 specifies types of filters that cannot be used unless the drug product cannot be manufactured, processed, or packed without their use, and also requires that in this eventuality the drug product be refiltered through a nonfiber-releasing filter.

XI. CONTROL OF COMPONENTS AND DRUG PRODUCT CONTAINERS AND CLOSURES

GENERAL REQUIREMENTS

199. Several comments suggested that the requirements for containers and closures in proposed §§ 211.80(a) and 211.89 be separated from those for components and in-process materials because the testing controls, systems, and criteria differ.

The Commissioner finds that the control of in-process materials is more appropriate in Subpart F—Production Process Controls; therefore, all references in Subpart E to in-process materials are deleted. Proposed § 211.88 and certain requirements proposed in § 211.89 are now in § 211.110(c) and (d). It is appropriate to consider control of components, drug product containers, and closures together, however, because the separation of requirements for control of containers and closures from components in the CGMP regulations would necessitate the unwarranted duplication of numerous sections of text. The variations in handling, examining, or testing can be adequately addressed by each manufacturer in the written procedures required by the various sections.

200. One comment argued that these proposed requirements in Subpart E would place an additional burden on small manufacturers and that such requirements are unnecessary, particularly with OTC pharmaceuticals.

Drug product containers and closures play a critical role in assuring that the patient is provided a drug product of essentially the same strength, quality, and purity as when it was produced by the manufacturer. The Commissioner cannot agree that OTC drug products should not receive the same degree of protection as prescription drug products. It has been FDA's experience that "small" manufacturers can attain the same degree of quality of their drug products as large manufacturers. There cannot be different standards of quality of drug products for large and small manufacturers, nor can there be different standards of quality for OTC and prescription drug products.

201. One comment on § 211.80(a) raised several issues relative to the handling of bulk components being held in storage tanks or silos, including the commingling of a new shipment with the remainder from previous shipments and how such lots should be identified.

Combining a new bulk shipment of a component in a bulk storage tank with the remainder of a previously received, tested, and approved component lot causes the compositing of the material. The result is that the previously approved material becomes in integral part of an unapproved new lot and cannot be used until such lot is approved for use. However, a manufacturer may choose not to commingle approved lots with unapproved lots of components in bulk storage. In some instances a manufacturer may be able to test components appropriately before introduction to bulk storage as, for example, when a shipment of components is received with a valid certificate of analysis and where identification testing may be sufficient.

202. Some comments suggested deletion from § 211.80(a) of the words "in detail" because it would require the documentation of minutiae and voluminous written procedures.

The Commissioner agrees that the phrase "in detail" could be construed to include description of insignificant protions of the procedure, which is not the intent. Therefore, he is inserting the word "sufficient" before the word "detail."

203. Comments were received on § 211.80(a) recommending replacement of the phrase "approval or rejection" with the word "disposition."

The Commissioner disagrees with this suggestion. Written procedures must spell out the criteria for approval or rejection in view of such material's intended use.

204. One comment suggested that the first sentence of § 211.80(a) be preceded by the phrase "where appropriate" to allow for the size and complexity of the operation.

The Commissioner believes that written procedures are appropriate regardless of the size or complexity of the operation. Written procedures provide a basis for the uniform performance of a function.

205. One comment suggested adding to § 211.80(b) the phrase "so as to alter the safety or efficacy of the drug product."

The Commissioner finds that it is reasonable to conclude that contamination would affect drug quality. Therefore, the suggested phrase is unnecessary and is not included in the final regulations.

206. Numerous comments strongly objected to the requirement in § 211.80(c) that components, drug product containers, or closures be stored at least 2 feet away from walls, maintaining that it would severely reduce the available storage area and thereby necessitate additional space to store the same amount of material with an attendant inordinate and unnecessary inflationary impact. Some of these comments suggested that this sanitation-oriented requirement be placed in § 211.56 or combined with § 211.80(b). Additionally, some comments offered alternate wording such as: to permit cleaning and inspection, to allow for appropriate sanitation operations, and to allow for effective sanitation practice. Some comments questioned whether this requirement only refers to outside walls or includes all walls, such as mesh screened walls, vault walls, partitions, and refrigerator and freezer walls. Some comments questioned whether free-standing shelves also had to be "at least 2 feet away from walls," since shelving is sometimes attached to the wall for safety reasons.

The Commissioner has carefully evaluated this paragraph in light of his intention to provide suitable spacing in storage areas for cleaning and inspection and concludes that a specific requirement for at least a 2-foot space between the wall and such material can be deleted, but a requirement to store materials in a way that allows for cleaning and inspection will be retained. He is also deleting the words "on pallets or free standing shelves" to allow for other suitable methods of storage. The Commissioner believes it preferable to codify this requirement in this section rather than in § 211.56.

207. Numerous comments on § 211.80(d) objected to the proposed requirement to identify each container in a lot being received since many items, such as containers, closures, and excipients are palletized. This requirement, as proposed, would mandate that each pallet load be broken down so that each unit on the pallet could be identified, then repalletized, thereby increasing the potential for damage and mixups. This procedure is alleged to have an unnecessary inflationary impact.

The Commissioner recognizes that there are situations where it would be inappropriate to identify each container of component, drug product container, or closure such as mentioned in the proposed regulation. He agrees that some provision should be made for these situations. He is therefore amending this paragraph by adding the words "or grouping of containers." Any individual unit separated from a grouping must be identified with the appropriate information required by this paragraph.

208. Some comments requested a clarification of the word "disposition" in § 211.80(d) that would distinguish between a simple transfer of the material and use of the material for a particular purpose.

The Commissioner believes that the word "disposition" appropriately covers any use or change in control status of the lot, including both of those cited in the comments.

209. Some comments questioned the intent of the last phrase of § 211.80(d). The respondents stated that if the intent is to identify those containers that have been opened, then a period should be placed after the parentheses and a suggested new sentence added to clarify the intent.

The Commissioner agrees that this phrase could be interpreted to require that only the lot be marked to indicate whether and when it had been opened and sampled. The requirement for the sampling of lots is contained in § 211.84. Therefore, he concludes that the requirement in § 211.80(d) regarding identifying sampled containers is more appropriately placed in § 211.84(c), which will clarify the intent to identify containers which have been sampled.

210. One comment on § 211.80(d) suggested that when a shipment of components contains more than one manufacturer's lot number, the recipient be allowed the option of assigning a single code number for this shipment.

The Commissioner rejects this suggestion inasmuch as it would either complicate or negate tracing a component back to a particular manufacturer's lot or the subsequent tracing of a particular lot of component used to a lot of drug products.

211. One comment objected to the requirement in § 211.80(d) that containers of drug product containers bear an identifiable lot number, on the grounds that this is not standard practice in the industry. The comment suggested that the recipient provide a distinctive code for such containers.

The requirement is that each lot of each shipment be identified with a distinctive code. If a lot number furnished by the supplier is distinctive for each lot in each shipment, then the recipient, i.e., the drug product manufacturer, can use the lot number as the distinctive code. If, however, there is no lot number or the lot number is not distinctive for each lot in each shipment, then the recipient is responsible for designating his own distinctive code.

RECEIPT AND STORAGE OF UNTESTED COMPONENTS, DRUG PRODUCT CONTAINERS, AND CLOSURES

212. One comment proposed that § 211.82(a) be divided to cover components, and containers and closures separately.

The identification of articles received, camparison with materials ordered, and examination of the overall condition of the material received is carried out in much the same way regardless of the character of the article received. The Commissioner sees no advantage to promulgating two separate regulations on receiving and storage of materials, one for components, and the other for containers and closures. To do so would simply be redundant.

213. A number of comments on § 211.82(a) said individual containers of components, containers, and closures need not be visually examined before acceptance as long as they are checked before use. The rationale for the comments is that a visual check of each container is impractical and unrealistic for large shipments of bagged materials that are palletized as a unit and/or shrink-wrapped. The respondents suggested that tearing apart materials packaged in that manner would be costly and could be better done before use rather than in a receiving area.

It was the Commissioner's intent in this paragraph to provide for a simple check at the time of receipt to detect obvious problems such as the wrong article, damaged containers, or visible contamination which would preclude any further handling of the materials. He recognizes, however, that individual container examination of large lots of bagged or boxed materials is impractical when they are received. Therefore, this requirement is revised to provide for examination of each container or grouping of containers.

214. A number of comments expressed concern over the possibility of contamination if containers of components and other materials are opened for examination in the receiving areas of factories. To avoid cross-contamina-

tion it was suggested that examinations be limited to the exterior of the containers or to shipping containers.

The Commissioner notes that this paragraph does not specify that seals must be broken for purposes of examination. It is the intent of this paragraph that a visual examination be performed. In most cases it would be adequate to limit the examination to shipping containers. If the firm feels an inspection should be made in depth, proper precautions must be taken to prevent cross-contamination.

215. Several comments in regard to § 211.82(b) objected to the concept of setting a special area aside for quarantined materials. They felt that reserving space for this purpose and moving stock into and out of this special quarantine area would be costly because of the additional space and labor required. Further, some felt that paperwork systems can accomplish quarantine purposes.

The Commissioner refers to the detailed discussion in paragraph 128 of this preamble that describes the variety and degree of physical quarantine procedures which, when combined with other controls, provide the assurance necessary to prevent untested and unreleased materials from being used in drug manufacturing operations.

216. Several comments on §§ 211.82(b) and 211.84(a) proposed that components should be "tested" whereas containers and closures should be "examined visually," and that the word "tested" should be deleted whenever it refers to containers and closures.

The Commissioner does not agree that appropriate testing of containers and closures can be limited in all cases to visual examination. Even in instances where visual examination would suffice, however, the word "testing" is meant to include such examination. Other CGMP regulations do use the word "examination" along with "testing" to suggest a lesser type of testing, if appropriate, however; and the Commissioner is therefore adding the phrase "or examined, as appropriate" to prevent any misinterpretation of §§ 211.82(b) and 211.84(a).

TESTING AND APPROVAL OR REJECTION OF COMPONENTS, DRUG PRODUCT CONTAINERS, AND CLOSURES

217. Citing various reasons, comments suggested that § 211.84(a) be revised to permit use of components, drug product containers, and closures, simultaneously with testing and with precautions to prevent release of the drug product until the tests indicate compliance with specifications.

As a general principle, such procedures would violate the precepts of good quality control because untested and possibly noncomplying materials would be used in drug product processing. Although initially it would appear that the manufacturer merely assumes the risk of having to recondition or destroy a processed lot that was found to contain unsatisfactory components, containers, or closures, the Commissioner is concerned that processing while testing substantially increases the risk to the consumer that an unsatisfactory lot might erroneously be released. The Commissioner cannot accept such risks or these suggestions.

218. Two comments on § 211.84 suggested that the only practical test of product container and closure acceptability is the actual use of them.

The Commissioner rejects the concept. He notes that there are techniques available and in use by which the suitability of a container-closure system can be determined before its use. Manufacturers do develop specifications for product acceptance when making their purchases. Such purchases are made with definite knowledge of what is needed. The regulation simply requires that checks be made to assure that what has been received is what has been ordered.

219. One comment suggested that a protocol or certificate from the container manufacturer that the container meets the U.S.P. requirements be acceptable in lieu of the recipient performing the tests.

The Commissioner notes that certificates or reports of analysis are acceptable for components with certain provisions, such as periodical verification of the supplier's test results. Therefore, he would have no reservation about accepting a certificate or report of analysis with each shipment of drug product containers—as long as the lot of containers is appropriately identified, the supplier's results are periodically verified, and their certificate provides all appropriate testing. A new paragraph, § 211.184(d)(3), is added to clarify this provision.

220. One comment interpreted § 211.84(a) to require that each lot of components, drug product containers, and closures be tested before each use in processing.

This paragraph does not require such a practice, nor is that intended.

221. Several comments questioned the meaning of container identification in § 211.84(a) and its relationship to a similar requirement in § 211.80.

The Commissioner is deleting the requirement regarding container identification from § 211.84(a) because such requirement more appropriately appears in § 211.80.

222. Several veterinary drug manufacturers responded that the testing requirements for drug product containers and closures in § 211.84(a) should not apply to veterinary drugs or that a very simple visual examination of such items would be all that is necessary for animal products. One comment said the requirements for containers and closures in Subpart E are not current good manufacturing practice for the veterinary drug industry.

The Commissioner does not accept the stated premise that the veterinary drug industry does not exercise such control over these containers and closures to ensure the protection of their drug products from external influences such as light, moisture, and microbes. The agency's experience in inspecting veterinary drug manufacturers and in reviewing new animal drug applications indicates that this is not so. The requirements of Subpart E can and should apply to both human and veterinary drug products.

223. A number of comments on § 211.84(b) objected to a requirement for the use of statistical criteria to determine the sample sizes for testing. Many of the comments recommended that the requirement be made optional or that it be applied only when necessary or appropriate. Some suggested that few people in the pharmaceutical industry understand statistical methods and that even experts differ on interpretation and application. One comment suggested that representative samples are impossible for all materials and suggested that random sampling be permitted.

The Commissioner believes that statistical methods provide a rational basis for determining sample sizes, provide assurance that an adequate sample has been obtained, and increase the user's confidence that the results from testing of the sample are representative of the true condition of the product sampled. The Commissioner recognizes, however, that other sampling plans, derived by other means, may also be adequate, and this section is revised to allow the use of alternative types of sampling plans. This will allow for use of random sampling methods if appropriate.

224. A few comments requested that containers and closures not be included in the representative sample requirement of § 211.84(b). No rationale was included to explain the request.

If the comments meant that other sampling methods such as random sampling are more appropriate, then the change made in this paragraph will be responsive to these comments. If the comments meant that containers and closures should not be sampled at all, the Commissioner rejects the comments because he believes that examinations must be made on product containers and closures to assure their suitability for use in drug product packaging.

225. One comment requested explanation of an acceptable "past quality history of a supplier," as suggested by § 211.84(b).

The Commissioner did not use the word "acceptable" in his proposal, but did permit the past quality history to be used in determining sampling plans for articles received from various suppliers. The object of considering the past quality history is that the fewer the problems encountered with materials from a particular supplier and the more often that supplier's products meet specifications, the less extensive the sampling schedule may need to be for that material. Conversely, the more problems encountered with articles from a particular supplier, the more extensive the sampling schedules for the articles need to be.

226. One comment suggested that the word "incoming" be inserted before the word "shipment" so that the sentence is clear that no reference is being made to outgoing shipments.

The Commissioner believes the meaning of the section is clear and that the sentence refers to materials received for use in drug production. Therefore, no change is made in the final regulation.

227. One comment suggested deletion of the reserve requirement in § 211.84(b) because such a requirement appears in § 211.170(a) and is appropriate only for components.

To clarify his intent here, the Commissioner is adding the words "where required by § 211.170."

228. Two comments recommended that the requirement in § 211.84(b) for testing each shipment of each lot is unnecessary when a previous shipment of the same lot had been received, tested, and approved.

The Commissioner feels that examination of each lot of each shipment received is necessary even though a portion of the same lot has previously been received, tested, and approved. Subsequent shipments may have been subjected to different conditions which may have caused changes in materials so that, although one shipment of a particular lot has met specifications, another may not.

229. Fifteen comments on § 211.84(c)(1) stated that containers from which samples are being collected do not always need to be wiped or vacuumed. In addition, two other comments requested deletion of all the paragraphs as unnecessary because all manufacturers know what they need to do.

The Commissioner agrees that a container of components may not always need cleaning before sampling and that, where cleaning is needed, wiping or vacuuming may not necessarily be the most effective means of cleaning. Therefore, he is revising § 211.84(c)(1) to provide manufacturers with more latitude in this operation. The Commissioner does not agree, however, that controls used in sampling are uniform throughout the pharmaceutical industry. Some manufacturers already have the controls required here, while others do not. Therefore, this requirement is appropriate in the CGMP regulations.

230. Several comments suggested inclusion of additional controls in this section as follows: provisions for handling sterile materials; a requirement that each container that is sampled be marked; and identification of the location within a container from which a sample was taken.

The Commissioner believes that the proposed requirements, with one exception, provide sufficient control of sampling procedures. The language of this section is general to allow for a wide variety of methods of handling products with a wide variety of characteristics. It is not the Commissioner's intent to design a specific control procedure which a manufacturer must follow, or to preclude flexibility in meeting this objective. It is sufficient here to state the control desired and leave the specifics to the reasonable judgment of the manufacturer. The Commissioner believes that the suggestion for identifying the locations within a container where samples have been taken is inherent in § 211.84. To clarify that containers from which samples are taken must be marked in order to produce an appropriate record, the Commissioner is adding a new § 211.84(c)(6).

231. A number of comments were received on § 211.84(c)(4) relating to component subsampling and compositing of subsamples. The majority of those commenting recommended that the regulations allow for compositing. Some respondents stated that sampling at multiple levels is not always necessary. Others suggested that the instances be spelled out where sampling at multiple levels is necessary. One comment indicated that compositing is a satisfactory procedure if the container contents are all going to be used in a single drug product lot.

The intent of this proposed section is to prohibit the compositing of samples taken from different portions of a container when there is a possibility that the composition of the material being sampled may vary within the container. There is no general prohibition in the regulations on compositing samples where such compositing would not mask subdivisions of the sample that do not meet specifications.

232. A number of comments suggested changes in the requirements proposed in § 211.84(c)(5) for identifying the sample containers. Three comments objected to the proposed sample container identification as being too burdensome because the information is available in other documents. One comment suggested that an in-house code to identify samples is adequate. Another said that the proposed sample container identification is not a current good manufacturing practice.

It is not the Commissioner's intent that all the listed information appear on the sample container. Section 211.84(c)(5) is reworded to require only a means whereby sample containers can be related to the required identification information.

233. One respondent expressed concern that the requirement for opening containers for sampling in a suitable area would lead to separate areas for each ingredient.

This paragraph is revised in the final regulation, and the words "suitable area" are deleted.

234. One comment suggested deletion of the word "containers" in § 211.84(c)(2) dealing with cross-contamination because the requirement should relate to the contamination of components and not containers.

The Commissioner agrees that the protection from contamination, as required in § 211.84(c)(2), should relate to the contents of sampled containers. The final regulation is clarified in this regard.

235. Twenty-eight comments on § 211.84(d)(1) stated in essence that the word "specific" should be deleted with reference to identity tests because there may not be specific identity tests for each component. The words "appropriate" and "if available" were suggested for use instead.

The Commissioner recognizes that the accuracy and precision of testing procedures vary. The purpose of § 211.84(d)(1) is to assure that some identification procedure is used for each component and that it is as specific as possible. Otherwise, the test has little value for purposes of identifying a material. This paragraph is reworded in recognition that specific identify tests do not exist for all materials.

236. One comment said interpretation problems could occur with the identity test requirement for active and inactive ingredients in § 211.84(d)(1) in multiple-ingredient components. The suggestion was made that the wording be changed so that an identity test for each component had to be performed whether it was an active or inactive ingredient.

The Commissioner is clarifying § 211.84(d)(1) in the final regulation by requiring at least one test to verify the identity of each component of the drug product.

237. Five comments said there should be no requirement in § 211.84(d)(1) for an identity test for inactive components.

The Commissioner believes it is important to identify inactive components to avoid erroneously using unsuitable components to manufacture a drug product.

238. The use of organic chemical reactions as indications of product identity in bulk chemical processing was recommended by one respondent as an acceptable identity test under § 211.84(d)(1).

The Commissioner advises that the final regulation does not preclude organic chemical reactions as indicators of component identity, if appropriate.

239. A number of comments relating to validation of a supplier's test results recommended that that portion of § 211.84(d)(2) be deleted. The argument was that the validation requirement would preclude the use of procedures other than those used by the supplier. One change in the wording was suggested: that the word "monitors" be used in place of "establishes."

The Commissioner believes that alternative procedures may be an acceptable means of validating methods used in the testing of materials by a supplier. The regulations do not preclude the use of alternative methods.

About the word "monitors" in place of "establishes," the Commissioner believes that the meaning of this sentence would be changed if the substitution were made. If a manufacturer wishes to rely on a supplier's report of analysis, the manufacturer must first establish that those reports are reliable. That reliability is established by the manufacturer's own testing which, when compared to the supplier's data, shows agreement within specified limits over a period of time. Once that reliability is established, then the level of the manufacturer's validation testing may be reduced and reliance on the supplier's report may increase. Continuing checks should be made on the supplier's reports because some kind of periodic monitoring must occur to assure the continued reliability of the supplier's test results.

240. One comment suggested that the word "complete" should be deleted from § 211.84(d)(2) as a descriptive term for the supplier's report of an analysis.

The Commissioner's intent in this paragraph is to allow for alternative routine testing where reliable reports of analysis are available for components. He finds that the criteria for accepting reports of analysis adequately provide for their proper application and that the modifying term "complete" is not necessary. The final regulation is revised accordingly.

241. One comment said suppliers' reports of analysis are not always reliable and suggested that several additional guarantees be required in § 211.84(d)(2). They included, in addition to the report of analysis, a guarantee of the type described in section 303(c) of the act, a certification that the testing reported was done within 7 days of the report, and a guarantee that at the time of shipment/receipt that the component will still conform to protocol specifications.

Suppliers' reports of analysis must be validated to establish the reliability of the suppliers' analysis. Additional specified requirements relating to supplier's test results do not now appear to be necessary for these regulations.

242. One comment expressed concern that the validation requirement in § 211.84(d)(2) would lock a manufacturer into a single supplier, presumably because of the investment in validation procedures.

The Commissioner advises that reliance on a supplier's report of analysis is not mandatory—it is optional in lieu of testing by the manufacturer. Although an investment in validation might persuade a manufacturer to remain with a single supplier, this does not constitute sufficient reason, in the Commissioner's opinion, to preclude the use of this approach by manufacturers. Competition among suppliers should not be adversely affected by this option.

243. One respondent proposed deleting the word "all" with reference to the phrase in § 211.84(d)(2) that testing be done in accordance "with all appropriate specifications," apparently to allow for less stringent testing if deemed appropriate by the manufacturer.

The Commissioner believes the suggested change would alter the meaning of § 211.84(d)(2). The intent is that appropriate specifications be established. Once appropriate specifications have been set, it is not acceptable to test for less stringent specifications.

244. A comment suggested deletion from proposed § 211.84(d)(3) (now § 211.84(d)(4)) of the reference to microscopic examination, stating that it does not seem to relate to any of the other provisions in this section.

The Commissioner recognizes that § 211.84(d) could list various other types of examinations, but he does not believe it inappropriate to specify a particular requirement for microscopic examination when appropriate, while not listing others. For certain classes of drugs, particulate contamination is of increasing concern. Identification and classification of particulate matter may properly require microscopic examination. Therefore, the Commissioner believes reference to microscopic examination is worthy of emphasis in the regulations.

245. Eleven comments on proposed § 211.84(d) (4) and (5) (now § 211.84(d) (5) and (6), respectively) indicated that requiring materials to be either approved or rejected after testing does not take into account other categories of material status into which materials could fall if they do not meet specifications. For example, comments said that materials could be reprocessed or approved for alternative uses and proposed that a revision be made to recognize these other possible classifications.

The Commissioner agrees that destruction may not be the only way of disposing of materials which do not meet acceptance criteria. If materials are being tested for their acceptability for manufacturing a particular drug product and they do not meet those criteria, however, they must be rejected for that use. This requirement has been set forth in § 211.84(e) now, rather than in (d)(5) and (d)(6). There is no prohibition against the use of such materials after appropriate reprocessing, or for other uses for which the acceptance criteria can be met.

246. One comment suggested that examination of material under proposed § 211.84(d)(5) be limited to visible contamination.

Other types of examination may be necessary to identify contamination, because contamination that is not visible may adulterate a material as significantly as visible matter. Therefore, the suggestion is rejected.

247. One comment suggested a new requirement be added to § 211.84(d) that representative samples of materials be examined for filth or microbiological contamination.

The Commissioner notes that other paragraphs in this section, particularly § 211.84 (a) and (b), require testing of representative samples. There appears to be no need to repeat it in § 211.84(d).

248. One comment said with regard to proposed § 211.84(d)(5) that it is the manufacturer's responsibility to determine the need for testing for microbial contamination.

The Commissioner agrees that it is the manufacturer's responsibility to determine what materials are liable to microbial contamination, but having made that determination, the manufacturer must proceed to test those materials for such contamination.

249. The requirement in proposed § 211.84(d)(5) for microbiological testing of materials liable to bacterial contamination was interpreted by one comment as requiring sterility tests for containers and closures used in aseptic filling operations.

The Commissioner agrees that an evaluation of a final production of

aseptically produced sterile products would include the testing of containers and closures. Once a procedure is validated, periodic testing and control monitoring are necessary to assure that the processing controls continue to work.

USE OF APPROVED COMPONENTS, DRUG PRODUCT CONTAINERS, AND CLOSURES

250. A substantial number of comments objected to the requirement that, without exception, approved components, containers, and closures must be used on a first-in, first-out basis. These comments pointed out, for example, that on occasion a manufacturer might wish to evaluate a new supplier, or equipment, or processes in relation to a new container; or that on occasion the oldest stock might be physically inaccessible for a short period of time. Several comments deemed the regulation unnecessary because some containers are inert.

The Commissioner believes that the concept of using the oldest approved stock of components, containers, and closures is fundamentally sound. Even inert containers may be subject to increased breakage, cracking, or other defects after prolonged storage. There may, however, be legitimate reasons for varying from this requirement in some instances. Therefore, this section is revised to provide for exceptions from the first-in, first-out requirement by adding a provision that deviation from this requirement is permitted if such deviation is temporary and appropriate.

RETESTING OF APPROVED COMPONENTS, DRUG PRODUCT CONTAINERS, AND CLOSURES

251. Several comments on § 211.87 did not agree that components, drug product containers, and closures should all be retested in accordance with established requirements. They maintained that components require specific retesting procedures to assure continued identification, strength, quality, and purity, whereas the likelihood of deviation of containers and closures from specifications because of deterioration is considerably less and should not require the same degree of retesting as components. They contended that stating requirements for retesting components and containers within the same section by the use of qualifying statements like "appropriately" or "as necessary" would weaken the former to accomodate the latter. They therefore proposed that this section be divided into two subsections, one for retesting components and a second for containers and closures.

The Commissioner believes that this section allows for different treatment of containers and closures versus components by use of the phrase "as necessary." The Commissioner recognizes that all the objectives of retesting listed in this section—to reestablish identity, strength, quality and purity—are not necessarily applicable to all containers and closures because all containers and closures are not necessarily tested originally for all these attributes. He also recognizes that the period for appropriate retesting varies not only according to conditions of storage, but also according to the type of component and the type of container and closure. The Commissioner retains the wording of the proposal in the final regulation.

252. One comment suggested that the words "or examined" be added after the word "retested" in § 211.87.

The Commissioner agrees that examination is not precluded by this section if examination is the appropriate test for the attribute being considered. Therefore, this section is modified in accordance with the respondent's suggestion.

REJECTED COMPONENTS, DRUG PRODUCT CONTAINERS AND CLOSURES

253. One comment recommended that in § 211.89 the words "lots of" be inserted between the words "rejected" and "components."

The Commissioner rejects this recommendation since the requirement applies to all rejected components, drug product containers, and closures whether they be lots, batches, portions of lots or batches, or otherwise identified.

254. Several comments suggested that this section be expanded to deal with the subsequent disposition of rejected materials.

The Commissioner notes that the criteria for reprocessing rejected materials are adequately covered in other sections of this part. It is not necessary to deal with other methods of disposition because they are varied, are within the manufacturer's discretion, and may include destruction, return to the supplier, or use in other products where specifications are met. The Commissioner believes the major concerns of FDA are that rejected materials are not inadvertently used in a product for which they are not acceptable and that any such materials that are reprocessed and found suitable for reuse meet specifications, standards, and characteristics for the intended use.

DRUG PRODUCT CONTAINERS AND CLOSURES

255. A number of comments asked about the meaning of the word "container" in § 211.94(a). For example, respondents inquired about the applicability of the proposed requirements to shipping cartons and containers for holding of in-process materials.

As recognized by the majority of comments received about this paragraph, the section heading introduces requirements regarding drug product containers and closures. The Commissioner finds that minor editorial changes in the text will clarify that this section is intended to apply to drug product containers. Requirements elsewhere in the regulations deal with appropriate handling of components and in-process materials.

256. Several comments on § 211.94(a) involved testing requirements for container and closure systems. One comment recommended that specific testing requirements be included in this section. Another comment said that once the suitability of a container-closure system had been established, it should not be necessary to test each lot in minute detail.

The Commissioner finds that specific detailed requirements for testing of the container-closure system are not necessary for this section. Usually, manufacturers already have the benefit of experience with containers fabricated from materials with well-known properties. Further, the requirement of § 211.166, particularly paragraphs (a)(4) and (b), will provide substantial information relative to the suitability of a container-closure system. Where the manufacturer does not have adequate information regarding the container-closure system, the responsibility is on such manufacturer to establish the suitability of the container-closure system for its drug product. The final CGMP regulations do not specify detailed testing of each and every lot of containers. Manufacturers are responsible for the extent and manner of sampling and testing of drug product containers and closures. Adequate sampling and testing of containers will depend on a number of factors. The duty of the manufacturer is to assure that the container-closure system meets appropriate specifications that have been established for a particular packaged drug product.

257. One comment suggested that § 211.94(a) also specify that the container-closure system "be clean."

Revisions in § 211.94(c) clearly provide for the use of clean containers and closures.

258. All of the numerous comments on § 211.94(b) requested that the requirement that container-closure systems "provide adequate protection" be modified to the limits of "normal" storage and use of the product or to limits of use and storage set forth on the label.

The Commissioner agrees that the proposed regulation requires a level of protection that may not be possible to achieve in unforeseen circumstances. Therefore, the final regulations are revised to include the concept of foresee-

able conditions. The Commissioner believes, however, that the acceptability of container-closure systems under a relatively narrow range of conditions that might be considered "normal" is not sufficient. It is reasonable for manufacturers to consider conditions that can be expected to occur occasionally; for example, extreme temperature variations that may be encountered during winter and summer months for drug products that are in transit can be reasonably foreseen by manufacturers and should be taken into account when considering the suitability of container-closure systems.

259. About 50 comments were received concerning § 211.94(c). Most suggested modification of the requirement that containers and closure systems always be cleaned before usage. Many indicated that although it was the drug manufacturer's responsibility to see that these items are clean, manufacturers may not always have to perform a separate cleaning operation. Examples of items which may not always need cleaning were cited, such as: caps, liners, blisters, neutralizers, and films.

In proposing this requirement, the Commissioner intended that containers and closures be clean before use. In some instances this will require the manufacturer to perform separate, and sometimes extensive, cleaning cycles. In other instances it may not be necessary for the manufacturer to undertake a specific cleaning operation. In any event, containers should not be released by the quality control unit, as specified in § 211.84(a), until procedures, standards, or specifications, established under § 211.94(d) have been met. To clarify the intent of this section the word "cleaned" is changed to "clean."

260. The majority of the comments regarding § 211.94(c) were directed at the requirement, currently in effect, that containers and closures be cleansed with water that has been filtered through a nonfiber-releasing filter of specified pore size. Comments strongly objected to this requirement for a number of reasons. A few read the paragraph as requiring that containers be recleansed with water, whether or not a cleaning cycle is necessary; several respondents noted that solvents other than water are used for cleansing; others objected to the pore size requirements because of high volume demands of cleaning cycles. In addition, arguments were presented that by requiring filtration of cleaning water for injectable containers, new problems of microbial and pyrogen contamination are possible.

In particular, the United States Pharmacopeia submitted comments by the Subcommittee on Particulate and Chemical Contamination, National Coordinating Committee on Large Volume Parenterals (NCCLVP), whose committee membership includes representatives from major health care organizations, industry, and government. The NCCLVP expressed concern that the requirement for filtered cleaning water presents disadvantages and potential hazards that far outweigh the benefits. The specific reasons for their concern are as follows:

1. Water lines for transferring cleaning water for injectable containers are designed, constructed, and maintained to deliver large quantities of high quality water under high pressures. In order to maintain the integrity of these lines and the quality of the water, disruptions must be minimized. The need to routinely install, test, and replace bacteria-retentive filters of the type required will undoubtedly compromise the integrity designed into these lines. Furthermore, the pressure drop resulting from the inclusion of such filters will jeopardize the quality of the wash.

2. Cleansing and rinsing procedures require copious volumes of water. Even with water containing low levels of microorganisms and particulates, significant accumulation of such contamination can occur on the filter surface. Proliferation of bacteria on the intact filter can lead to the generation of pyrogens or the growth of certain bacteria through the filter pores if a 0.45-micron filter is used. Since high flow rates and pressures are required, the chance for mechanical failure and breakage of the filter is increased, thereby increasing the risk for the passage of a bolus of bacteria.

3. Because of the microbial jeopardy described above, these filters will require scrupulous maintenance. Such efforts will result in significant penalties to the process in both material and labor costs.

It is the opinion of the Subcommittee on Particulate and Chemical Contaminants that if a fiber-releasing filter is not employed in the process and a final rinse is performed with high-quality, microbiologically controlled water, it would appear to be unreasonable to introduce the disadvantages described above.

The final regulation regarding asbestos particles in drugs for parenteral injection was published in the FEDERAL REGISTER of March 14, 1975 (40 FR 11865). At that time the Commissioner had concluded that it was prudent to require that containers and closures for human injectable drugs be cleansed with water that has been filtered through a nonfiber-releasing filter of a specified pore size. In view of comments received, the Commissioner is concerned that the requirement for filtered cleaning water may introduce new problems that outweigh risks of potential asbestos particle contamination from the container cleaning operations. The Commissioner notes that he raised a similar issue in the preamble to the CGMP regulations for large volume parenterals, published in the FEDERAL REGISTER of June 1, 1976 (41 FR 22202).

Because of the comments received, the Commissioner finds that there is substantial good reason to suspend, at least temporarily, the requirement that injectable containers and closures be cleansed with filtered water to remove fibers. The commissioner wishes, however, to serve notice that the issue of fiber removal from parenteral drugs, including where such fibers may be introduced through the cleaning cycle of containers, continues to be an important problem under review by FDA. Until FDA has additional information on the fiber content of cleaning water and the significance of such fibers, however, the final regulations are revised to delete the requirement for filtered cleansing water. But this action in no way affects the agency's position on fiber-releasing filters in the manufacture of injectable drug products for human use (see § 211.72).

261. Almost all the comments on § 211.94(e) said it was a restatement of the other parts of this section and therefore should be eliminated. One comment said the phrase "the holding of" was redundant since, by definition, containers are used "for the holding" of a product.

The Commissioner finds that the requirement of the proposed paragraph is not necessary in this section because a similar requirement appears in § 211.165(g). Therefore, he is deleting the proposed paragraph (e) from this section.

DOCUMENTATION OF CONTROLS

262. A number of comments suggested that § 211.96 be deleted on the grounds that it duplicates provisions of § 211.84.

The Commissioner agrees that both sections deal with documentation of the receipt, testing, or examination and disposition of components, drug product containers, and closures. Therefore, § 211.96 is deleted.

XII. PRODUCTION AND PROCESS CONTROLS

WRITTEN PROCEDURES; DEVIATIONS

263. One comment on § 211.100 said written procedures for manufacturing and quality control should be reviewed and approved by "the appropriate organizational units" instead of by the quality control unit because the quality control unit does not necessarily possess an expertise greater than that in other units. Another comment said the quality control unit does not have a sufficiently wide expertise to review and approve all areas of drug product manufacturing, including such areas as production, engineering, research, safety, and regulatory affairs. A third

comment said the requirement for approval of written procedures for manufacturing and quality control by appropriate organizational units other than the quality control unit should be deleted.

The Commissioner rejects these comments. He has not proposed that quality control have complete expertise in all of these areas. The requirement for review and approval of manufacturing and control procedures is clearly a requirement that the quality control unit review these procedures in light of what may affect the product in terms of safety and quality. To remove from the quality control unit the responsibility for approving written procedures would diminish the authority and responsibility that should be vested in the quality control function. Further, based on the agency's experience with the industry, the Commissioner believes that the concept of quality control review and approval for procedures that have a bearing on the quality and safety of a drug product is current practice. This section also properly requires review and approval by other appropriate organizational units. Therefore, the quality control unit's function does not replace the expertise that would be vested in other units.

264. Another comment on § 211.100 said requiring review and approval by the quality control unit is infringing unreasonably on individual manufacturers in determining their own organizational structures.

The Commissioner does not believe that this requirement unduly dictates organizational structure. For example, it does not designate to whom the quality control unit or other organizational units must report.

265. One comment on § 211.100(a) said appropriate units should be required to review, as well as draft and approve, manufacturing and control procedures.

The Commissioner agrees and is inserting the word "reviewed."

266. One comment suggested that the word "justified" in the last sentence of § 211.100(b) be replaced by the word "explained." Another comment proposed substitution of the word "approved."

The Commissioner believes that the word "justified" properly reflects the intent. All production and process control procedures must be approved, whether initial or subsequent changes. It is not necessarily enough to "explain" or "approve" a deviation. There must be a valid reason for a deviation.

267. One comment on § 211.100(b) said only significant deviations should be recorded and justified.

Section 211.100(b) requires that written procedures shall include all requirements as specified in subpart F of the CGMP regulations. This subpart does not require written procedures for every conceivable or minute detail of production and control. When such procedures are essential, the Commissioner maintains that any deviation from them is significant and should be recorded and justified. To modify the regulation as proposed would imply, however, that only some deviations are significant.

268. A comment proposed deleting from § 211.100(b) the phrase "and shall be documented at the time of performance."

Documentation of performance, in the Commissioner's opinion, certifies that the written procedures have been followed. He concludes that it is a necessary part of this section.

CHARGE-IN OF COMPONENTS

269. One comment on § 211.101 stated that the heading "charge-in of components" is an unfamiliar phrase and is not defined.

The Commissioner recognizes that not all firms use the same terminology to define similar phenomena. He believes the heading is clear when considered in light of the context of the section and that no change or definition is needed.

270. One comment said § 211.101 is addressed to dosage form production and cannot profitably be applied to chemical manufacture.

These CGMP regulations apply to finished dosage form drugs (under §§ 210.3(b)(4) and 211.1) and are not binding requirements for chemical manufacturing. The Commissioner maintains that these regulations can serve as useful guidelines in the manufacture of chemicals. The agency plans to develop specific CGMP regulations on production of bulk drugs.

271. One comment said it would be difficult to follow the requirements of § 211.101 when producing radiopharmaceuticals because the exact quantity of the radionuclide available before the production cycle begins is not known, and the components measurement must be performed aseptically.

The Commissioner is rewording § 211.101 to allow for its application to radiopharmaceuticals. Further, this comment will be considered when specific CGMP regulations are proposed for radiopharmaceutical drug products.

272. One comment said the operation supervisor may or may not be the same person as the one checking the operation and suggested adding a new paragraph (e) to § 211.101 to have the appropriate entries made on the batch record.

The Commissioner believes that § 211.188(b)(11) adequately covers this.

273. One comment said § 211.101(a) is ambiguous because the word "intent" needs defining. The respondent pointed out that antibiotic products are certified under published monographs permitting 85 or 90 percent of labeled claim as a basis for certification.

The Commissioner notes that this paragraph does not prohibit the release of batches of drug products if the percentage of active ingredients is within acceptable limits. The Commissioner recognizes that acceptable limits are in most cases a few percentage points above and below 100 percent of labeled potency. What is prohibited is the purposeful formulation of a product to yield less than the label declaration.

274. Several comments expressed concern that every active ingredient amount would have to be recalculated to provide 100 percent and that a new master production record would have to be prepared for each new lot of active ingredient because every lot of active ingredient may not have the same potency value.

The Commissioner believes that use of the word "intent" should be emphasized. Drug products must be formulated to provide 100 percent of labeled potency based on the usual assay of active ingredients. Active ingredients that are slightly above or below the usual value, but are within appropriate established specifications, may be used without reformulation provided that the resultant drug product will provide a percentage of active ingredient that is within acceptable limits. The criteria for acceptance of components should be such that proper use will result in an acceptable drug product.

275. One comment said it is extremely difficult to formulate a biological product to fulfill the requirement of § 211.101(a) because the potency value is assigned after the manufacturing process has been completed.

The Commissioner again emphasized the use of the word "intent." The example given in the comment does not show that there is intent to formulate such products at less than 100 percent of labeled claims; rather, it virtually precludes such an intent by the nature of that process.

276. One comment wanted to substitute the words "the amount of active ingredient specified in the master production and control record of the drug product" for the words "100 percent of the labeled amount of active ingredient" since over-the-counter drugs are not required by law to note the quantities of active ingredients in the labeling.

The Commissioner agrees with the object of the comment, but believes the suggested wording is inadequate

because it would not prohibit the master record from containing a formulation intended to provide less than 100 percent of labeled potency. Instead, the Commissioner is revising the final regulation by adding the phrase "or established" after the word "labeled." This would therefore include formulations established through new drug applications and over-the-counter drug monographs.

277. Many comments on § 211.101(a) said that: (1) It appears that all components must be weighed or measured precisely; (2) clarification of this section is needed to allow for the use of bulk components without previous subdivision, weighing, or measuring; (3) clarification is needed to allow for direct weighing of components into a batch.

The Commissioner finds that § 211.101(a) as written is not flexible enough to permit procedures such as are given as examples in the comments. Therefore, the first sentence of this paragraph is revised to read as follows in the final regulation: "Components for drug product manufacturing shall be weighed, measured, or subdivided, as appropriate."

278. Numerous comments requested clarification of § 211.101(b) regarding the necessary identification of component containers. The comments pointed out that in some instances components are dispersed, but that the manufacturing department would make that decision for specific batch usage. Several comments said the identification information was available through alternate control systems.

The Commissioner believes that, as written, the final regulation takes into consideration the physical dispersal of components. Comments that the required identification information is available through alternative control systems gave no examples; therefore, no change is made in the regulation.

279. Several comments objected to the word "strength" in § 211.101(b)(4) and wanted it deleted.

The Commissioner rejects these comments. If a component container does not adequately identify the batch in which the component is to be used, there is a potential for mixups. The term "strength" is defined in § 210.3(b)(16), so there can be no ambiguity in its meaning.

280. Two comments suggested that use of component lot numbers and product lot numbers on the same container presents a possibility of mixup since the wrong numbers may be written on the batch record.

The Commissioner finds that it is necessary to have this information for a complete drug product history. As a practical matter the requirement will probably not pose a problem because most firms already have number identification systems that readily distinguish component lot numbers from drug product batch or lot numbers.

281. Several comments objected to the requirement in § 211.101(c) that each container of component dispensed to manufacturing be examined by a second person.

The Commissioner believes the requirement is necessary and does not believe it will be a burden to the industry. The Commissioner also notes that the substance of the requirement is no different from that stated in § 211.40(a) of the CGMP regulations currently in force, and it reflects current industry practice.

282. Several comments said that in some cases, such as with bulk component systems, there are automated methods for checking that could replace a second manual check.

The Commissioner wishes to point out that the use of automated systems is permitted under § 211.68. The requirement of this section would be met if the second individual verifies that the automated system is working properly.

MANUFACTURING INSTRUCTIONS

283. Some comments suggested deleting § 211.102 because the subject and intent are adequately covered by § 211.100.

The Commissioner agrees with these comments, and this section is deleted in the final regulation.

CALCULATION OF YIELD

284. Several comments on § 211.103 said the requirement for determination of yields at each distinct phase of manufacturing, processing, packing, or holding is ambiguous and subject to varied interpretations in view of the agency's use of the terminology "each distinct phase." Others said some type of drug products do not lend themselves to a determination of yield at each distinct phase of manufacturing, such as certain biological products and those operations using continuous runs.

The Commissioner agrees because what is "distinct" is subject to different interpretation and not applicable in other cases. Therefore, he is revising the section to require yield determination at each "appropriate" phase of production.

285. Several comments said the requirement in § 211.103 for independent verification by a second person is unnecessary.

The Commissioner finds that independent verification is a current practice and has been, in substance, a CGMP requirement since 1963. Independent verification has been found to be a valid means of uncovering errors which might, if left undetected, adversely affect drug product quality. Therefore he rejects these comments.

286. Several comments said, in substance, that calculating the percentage of theoretical yield is not the only method of comparison.

The Commissioner does not believe that the wording as proposed would preclude the use of, for example, a standard range of acceptable yield. Ultimately, however, acceptance must be based on a ratio of actual yield to theoretical yield.

EQUIPMENT IDENTIFICATION

287. Several comments on § 211.105 pointed out that there are cases where several pieces of equipment are grouped together to perform a function and that in such situations, collective identification of the equipment should be sufficient rather than identification on individual components of the grouping.

The Commissioner feels that such a procedure is acceptable only if the equipment is permanently installed and used only for one purpose and only one batch of a drug product can be processed on it at one time. This procedure would eliminate the need to identify equipment when there could be no misunderstanding as to what drug product is being processed. In such cases of equipment dedication, identification of the grouping can be considered as meeting the requirements of this section. The language of the final regulation more clearly provides for this situation.

288. One comment requested clarification of the terms "production" and "major equipment" as used in § 211.105. The comment questioned whether equipment for label printing, insert folding, or other similar operations not used in dosage form preparation should be identified in the batch record.

Operations such as label printing and insert folding are not generally performed as a function of the production of a particular batch of drug product. Such operations are not suitable for consideration under § 211.105, but are subject to the requirements of § 211.122. The phrase "major equipment" is used in § 211.105 to distinguish it from minor equipment such as spatulas, ladles, and scoops, for which a requirement for identification may be unreasonable. Because it would be impractical to categorize every known piece of drug manufacturing equipment, a determination as to what equipment should be identified must be based by the manufacturer on appropriate criteria.

289. A number of comments on § 211.105(a) questioned the meaning of the term "processing lines" and requested a definition.

The term "processing lines" is used in a broad sense to include the variety of equipment that may be used in a drug manufacturing plant. For example, it may include a liquid filling "line" or a packaging "line" or any other kind of "line" used to convey a product through an operation, or to and from an operation, such as a pipe used to carry liquid from a bulk tank to another part of the plant.

290. Several comments on § 211.105(b) suggested that where a manufacturer has only one of a particular type of equipment, it is unnecessary to use a distinctive code or number to identify it in the batch records. It was recommended that the equipment could simply be named.

Since the intent of the code or number is to provide identification of the specific equipment used to process a drug product, the Commissioner has no objection to identifying the equipment by name under conditions specified in the comment. Wording of this paragraph in the final regulation provides for identification of equipment, under certain circumstances, by name.

SAMPLING OF IN-PROCESS MATERIALS AND DRUG PRODUCTS

291. Many comments on § 211.110(a) pointed out that all in-process tests identified in the proposal were not appropriate to all dosage forms.

It was not the Commissioner's intent to require that the particular tests listed apply to all dosage forms. The tests identified were meant to be examples of the types of tests that should be run on various dosage forms, but were not necessarily appropriate to all. Therefore, to make his intent clear, this paragraph is revised to show that these controls shall include those listed, where appropriate.

292. Two comments on § 211.110(a) indicated that the word "manufacturing" should be modified by the word "major" and that the word "variability" should be modified by the word "significant."

The Commissioner is not changing the wording because minor manufacturing problems may cause major manufacturing defects.

293. One comment recommended that the first part of the opening sentence in § 211.110(a) be deleted because procedures do not assure batch uniformity and integrity of drug products.

The Commissioner agrees that the written procedures do not in themselves assure drug product quality—the procedures must be administered to have an effect. The Commissioner notes, however, that the requirement includes that established procedures be followed. Therefore, the comment is rejected.

294. Several comments suggested deleting or revising the references in § 211.110(b) to statistical methods for determining in-process specifications. Some comments said statistical procedures for this purpose were not well understood either by industry or by FDA. Others said other means of determining in-process specifications should be allowed in addition to statistical means. One comment said manufacturers with tight limits and little batch variability would be penalized by this requirement. Another comment was that, because finished product specifications are arbitrarily derived, use of statistical techniques during in-process phases would be inappropriate. Several comments indicated that, in the case of new products or new manufacturers, there is no manufacturing history so other means of developing in-process specifications should be permitted.

The Commissioner is persuaded that there are other valid means of developing in-process specifications as alternatives to statistical methods. Therefore, the final regulation is revised to provide for the application of statistical procedures, when appropriate. The Commissioner emphasizes, however, that in-process specifications must be meaningful in terms of achieving the desired finished product characteristics. Further, after product histories are developed, the Commissioner encourages manufacturers to perform statistical analyses on their products and processes with a view to controlling batch-to-batch variability to the maximum extent possible.

295. Three comments suggested that § 211.110(b) requires in-process testing, whether needed or not, but that paragraph (a) only requires testing in an optional sense.

The Commissioner recognizes that there are instances where the effect of variability during drug manufacturing phases cannot be predicted in relation to the drug product. Further, there may be instances where there are no suitable points, during in-process phases, to sample and test. The final regulations are reworded to clarify this.

296. One comment suggested that allowance be made in § 211.110(b) for the use of in-process tests for adjustment purposes.

The Commissioner finds that specific references to in-process tests for adjustment purposes are unneccessary. The regulations provide flexibility to the manufacturer for establishing procedures for any appropriate in-process test and determining the significance of testing results.

297. As noted above in paragraph 199, the Commissioner concurred with recommendations to transfer requirements for in-process materials in proposed §§ 211.88 and 211.89 from Subpart E to Subpart F in new § 211.110(c) and (d). comments on the proposed sections will be addressed in this section of the preamble, using the new section numbers.

298. A number of comments suggested that § 211.110(c) (proposed as § 211.88) is overly restrictive because it would require complete testing of in-process materials at each significant step in production. It was suggested, too, that in-process testing done during production to determine the need for equipment adjustment or to monitor equipment adjustment need not be reviewed by the quality control unit.

The Commissioner concludes that the intent of this section, as modified in the final regulation, is clear. There is no requirement that the quality control unit approve or reject in-process materials at the completion of each and every individual test or examination. Approved written procedures may provide for minor equipment adjustments, checking, and monitoring of in-process material production. However, at the completion of a significant phase, for example, the quality control unit must approve or reject the in-process material before proceeding to the next phase.

299. One comment suggested defining the terms "significant stages" and "long periods" in proposed §§ 211.88 (now 211.110(c)).

To maintain the flexibility necessary for these regulations, the Commissioner finds that it would not be practical to define either of these terms because they can cover many types of situations and products. They should be read within the context of the handling of specific products and the characteristics of those products. A long period for holding an unstable product is obviously going to be quite different from a long period for holding a very stable product. In the same way, significant phases in the processing of drug products can vary greatly depending on the methods used and nature of the individual products. The determination of what is a "significant phase" and a "long period" must therefore be the responsibility of the drug processor.

TIME LIMITATIONS ON PRODUCTION

300. Several comments on § 211.111 said there may be situations, such as mechanical failures or when material in bulk form has to be remixed, where the processing time would of necessity be extended beyond previously established limits.

The Commissioner is revising this section to provide that deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug prod-

uct. Such deviation must also be justified and documented.

301. One comment suggested that the words "when appropriate" be deleted from § 211.111, placing the burden of time limits on the manufacturer in all instances.

The Commissioner rejects this suggestion in view of the general nature of these regulations. There may be instances where establishing time limits for production would serve no practical purpose in assuring drug product quality.

CONTROL OF MICROBIOLOGICAL CONTAMINATION

302. A respondent said that the requirements of § 211.113(a) are redundant for "chemical processing" operations.

The Commissioner is not sure what the comment meant by "chemical processing," but believes the comment may refer to in-process materials. If that is the case, the Commissioner does not agree. The possibility of microbiological contamination is an important concern in drug products, both nonsterile and sterile, and requires emphasis in the regulations to assure that special precautions are taken, over and above other precautions to assure product acceptability, and to assure that no microbiological contamination occurs during processing which could have an adverse effect on the drug product.

303. One comment said § 211.113 should not apply to medical gases because microbiological contamination is not a problem with such drugs.

The Commissioner notes that there is little information available in the literature on microbiological and particulate contamination of compressed medical gases. If microbiological contamination is not a problem with such drug products, then appropriate procedures may be less extensive than those needed for more susceptible drug products.

304. Several comments requested clarification of the term "objectionable microorganisms" as used in § 211.113(a) or suggested alternative descriptions of objectionable microorganisms such as harmful or pathogenic and fecal indicator microorganisms.

The Commissioner deliberately chose the word "objectionable" as the appropriate modifier for the term "microorganisms" in this paragraph to cover a number of circumstances. Microorganisms could be objectionable by virtue of their total numbers or their detrimental effect on the product or by their potential for causing illness in the persons ingesting them. A definition of the term is not practical in the regulations, however, because the objectionable nature of a microorganism may develop only in relation to the unique circumstances of a particular formulation, a particular ingredient, a particular method of manufacture, or the conditions found at a particular firm. The Commissioner believes that the use of the word "objectionable" in a very broad sense is a more practical means of expressing the kind of control he intends.

305. One comment recommended that § 211.113(b) be separated into two parts: Paragraph (b) would then apply to products manufactured by a sterile fill operation, and a new paragraph (c) would apply to a terminal sterilization process.

The Commissioner believes this paragraph, as written, can apply to both sterile fill process and terminal sterilization process. In both instances there must be validation of the process used to show that it produces a sterile product.

306. One comment suggested that § 211.113(b) would require the manufacture of nonsterile products under the same conditions required for sterile products. The comment further said that in some cases smaller numbers of microorganisms could be tolerated if kept under certain levels that could be established.

The Commissioner emphasizes that it is not his intent to require nonsterile products to be produced under sterile conditions. He has previously explained under paragraph 304, his intent in using the word "objectionable." Section 211.113(b) clearly states that it applies only to drug products purporting to be sterile.

REPROCESSING

307. Two comments suggested that the word "appropriate" be inserted before the phrase "established standards" in § 211.115(a).

The Commissioner finds that the suggested alternative wording offers no improvement over the proposed wording. Reprocessed batches must meet all established standards, specifications, and characteristics.

308. One comment suggested that the word "all" be deleted from § 211.115(a) after the phrase "conform with."

The Commissioner believes that the paragraph, as proposed, clearly states the intent regarding conformance with all established standards, specifications, and characteristics. Therefore, this suggestion is rejected.

309. One comment suggested alternative wording in order to clarify that § 211.115(a) applies only to batches that are reprocessed.

The Commissioner agrees with the substance of this comment and is adopting in part the alternative wording by revising the first three lines of § 211.115(a). The Commissioner notes that the requirements for handling batches that are not reprocessed are adequately stated in other sections under Part 211.

310. A number of respondents objected to the direct authority given to the quality control unit under § 211.115(b) in approving the reprocessing of nonconforming batches. They believe that such rejected batches should be either reviewed and approved subject to all normal tests by quality control or should be allowed to be reprocessed when the written procedures approved by quality control authorize and set forth the criteria for such reprocessing.

The Commissioner rejects these comments because they would not be consistent with accepted quality control practices. Reprocessing of drug products suggests that a problem occurred during production of a particular batch. The Commissioner does not believe it is reasonable to expect that preexisting reprocessing procedures can be written to cover every reprocessing situation. Therefore, it is appropriate that individual reprocessing procedures be reviewed and approved by the quality control unit.

XII. PACKAGING AND LABELING CONTROL

311. Many comments suggested changing the title of this subpart to "Printed Packaging and Labeling Control." Some comments suggested inserting the word "printed" before "labeling and packaging materials."

The Commissioner disagrees with the suggestions to change the title since this subpart includes controls for packaging materials that are not labeling. Insertion of the word "printed" to precede the word "labeling" would be confusing because, under section 201(m) of the act, labeling is written, printed or graphic material.

MATERIALS EXAMINATION AND USAGE CRITERIA

312. Several comments stated that the term "packaging materials" in § 211.122 is too broad in that it would include such items as corrugated dividers, pads, and blister-packing liners.

The Commissioner advises that the term "packaging materials" as used in this subpart refers to packaging materials other than containers and closures covered under Subpart E. Typically, unlabeled packing materials do not have to be examined as thoroughly as labeling materials. The Commissioner intends that § 211.122, as written, allow for different treatment of unlabeled packaging materials and labeling materials.

313. There were several comments regarding §§ 211.122, 211.186(b)(8) and 211.188(b)(8), stating that the word "labeling" is too broad because it could be construed as including advertising and promotional material and

therefore is beyond the purview of the proposed CGMP regulations.

As previously discussed in paragraph 96, the regulations in this part set forth the facilities, methods, and controls to be used for the manufacture processing, packing, or holding of a drug product. Therefore, these regulations do not apply to labeling or advertising that is not associated with the drug product during its preparation under CGMP regulations.

314. One comment said § 211.122 does not represent current practice, and no need for the proposed language has been demonstrated.

The Commissioner notes that this section, as finalized, does not differ substantially from existing requirements. He believes this section represents current good manufacturing practice and is a significant aspect of any firm's quality control program. He also believes that drug product recalls initiated because of packaging and labeling errors indicate that the controls described in this section are needed.

315. One comment suggested that the last sentence in § 211.122(a), pertaining to release of packaging and labeling materials after approval by the quality control unit, be replaced. The respondent believes that the use of unreleased lots of labeling and packaging materials should be permitted as long as approval is obtained before marketing.

As discussed earlier in this preamble, in paragraph 217 regarding use of unreleased components, drug product containers and closures, the Commissioner cannot accept this suggestion. It is not acceptable quality control practice to use unreleased materials in any phase of production. The Commissioner believes that use of released components, in-process materials, containers and closures, labeling, and packaging materials is generally regarded by manufacturers as necessary to quality control.

316. Several comments recommended deletion from § 211.122(a) of the words "in detail," and one comment said that, as written, the paragraph would require documentation of all minute details.

The Commissioner recognizes that different materials such as unlabeled packaging material, as opposed to labeling, will require written procedures of different degrees of complexity regarding their receipt, identification, storage, handling, and examination and/or testing. Therefore, the Commissioner is revising the phrase "in detail" to "in sufficient detail."

317. One comment understood § 211.122(a) to require the quality control unit to examine each container of material before acceptance. The comment recommended statistical sampling of materials instead.

The Commissioner advises that the degree of sampling will depend on the material to be examined or tested. The intent of this paragraph is to require at least a representative sampling of all labeling and packaging materials. The final regulation is clarified in this regard.

318. One comment recommended deletion of the first sentence from § 211.122(b), as it is redundant based on the requirements cited in § 211.122(a).

The Commissioner believes that § 211.122(b) as proposed clearly spells out the basis for approval or rejection and clearly states that rejected materials shall not be used in operations for which they are unsuitable. Therefore, he does not believe paragraph (b) to be redundant.

319. Two comments said § 211.122(b) is overly restrictive in that it requires labeling or packaging materials not meeting specifications to be rejected even though the rejection may not be based on a serious defect, and thus the material could be used.

The Commissioner asserts that it is up to the firm to establish appropriate specifications. These specifications should be realistic so as to assure the safety and quality of the drug product, but they need not be so restrictive as to prevent the use of materials that could not affect the safety or quality of the drug product.

320. One comment interpreted § 211.122(b) to tacitly allow use of a provisional release concept for materials that are found to be out of specifications for their original use but would be suitable for use in other operations. Therefore, the comment said this concept should be stated explicitly in the regulations.

The Commissioner does not believe that this paragraph implies the acceptability of any kind of provisional release. Materials rejected for one use must be completely tested and/or examined to determine their suitability for any alternative use prior to such alternative use.

321. A comment said labeling and packaging materials approved for use should be rotated so that the oldest approved stock is used first.

The Commissioner agrees that use of the oldest stock first is a desirable practice for most materials. The attributes of these types of materials that are related to age, however, do not normally have an effect on the drug product, as would be the case with components, containers, and closures. Therefore, the Commissioner has decided that a mandatory requirement for using the oldest stock first is not necessary here. He has required, though, in § 211.122(e) that obsolete labeling be destroyed.

322. A number of comments on § 211.122(c) said this is not current industry practice, that costs outweigh benefits, and consequently the paragraph should be deleted.

The Commissioner agrees that the proposed requirement for disposition, including dates and personnel involved, is unnecessary for packaging materials and believes that it was those proposed requirements that were for the most part being objected to. Further, § 211.125 establishes the more specific control requirement for labeling. Therefore, § 211.122(c) is modified to require only that records be maintained for labeling and packaging material indicating receipt, examination, or testing, and whether accepted or rejected. Many firms already record this information. The burden on firms not recording such information should not be too great because a record of this information is currently required for components; therefore, the firms need only incorporate packaging and labeling materials into the system already employed for components.

323. Several comments on § 211.122(d) wanted the exclusion of packaging materials other than labeling and a less restrictive wording than "separate compartments" for labeling.

The Commissioner is convinced that it is not necessary in most instances to separate unlabeled packaging materials in the same manner as labels and other labeling. Therefore, § 211.122(d) is revised in the final regulation to apply to labels and other labeling only. The Commissioner is also replacing the phrase "separate compartments" with the word "separately" because it may not be feasible to place into compartments bulky packaging materials that are labeled and therefore considered labeling.

324. One comment requested deletion of the phrase "or quantity of contents" in § 211.122(d).

The Commissioner rejects this request since labeling with different quantity-of-contents statements is in fact different labeling.

325. Many comments suggested deletion of § 211.122(e) as redundant. Other comments objected to the word "destroyed."

The Commissioner considered the comments and is convinced that this paragraph should be revised to avoid repeating requirements of § 211.122 (a) and (b). The final regulation refers only to obsolete and outdated labels, labeling, and packaging materials. Obsolete and outdated labels, labeling, and packaging materials must be destroyed to eliminate mixups between currently used labels, for example, and obsolete labels. Such mixups can lead to serious mislabeling incidents.

326. Five comments on § 211.122(f) contended that gang printing is not a good manufacturing practice and should be forbidden.

Although the Commissioner wishes to discourage gang printing, he does recognize that, under stringent controls, gang printing can be safely used.

327. Two comments dealt with monitoring of the printing procedure in § 211.122(g). One said it should be worded "* * * shall be set up by one person and be inspected by a second person at the beginning of the run to assure * * *" and the other suggested "* * * shall be monitored by the QC unit to assure * * *."

The word "monitor" is being used here to describe an in-process production check on a piece of equipment to assure that it is working properly. In such a case, the "monitoring" can appropriately be done by someone on the production line. The Commissioner notes that § 211.134 (a) and (b) contains a requirement for further examination for proper labeling. The Commissioner sees no need to revise this requirement.

LABELING ISSUANCE

328. One comment assumed that in § 211.125 the term "labeling" must apply only to items associated with the unit package. It further said there is nothing to be gained by accounting for any advertising that is included with OTC packages or shipping cartons simply because of the legal definition of labeling under the act.

The Commissioner advises that if the printed material referred to by the respondent is advertising under the act, then the CGMP regulations do not apply. However, as has been discussed previously, where labeling associated with a drug product during its preparation under CGMP regulations is involved, then the regulations in this section apply.

329. One comment questioned the meaning of "strict control" in § 211.125(a) and recommended that this paragraph be expanded to include certain specific features of strict control, such as requiring locked labeling transport containers.

The Commissioner believes that it would be impractical to list specific features of strict control that would relate to all firms. Numerous comments were received that objected to specifying a "how to" approach instead of an "objective" approach. This is an instance of the regulations stating an objective that is sought and leaving the method of attaining that objective to the reasonable discretion and ingenuity of the firm. The Commissioner, therefore, rejects this recommendation.

330. One comment recommended that the words "and/or batch" be inserted in § 211.125(b) after the word "master" because the master record does not contain the information regarding the lot number or the expiration date to be placed on the label.

The Commissioner notes that the intent of this paragraph is to ensure that the proper labeling is issued to the batch. He agrees that, as this comment points out, it is the batch record that usually contains the lot or control number and the expiration date and is therefore amending the paragraph to provide for this situation by including the words "or batch" after the word "master."

331. Some comments on § 211.125(c) asserted that labeling reconciliation does not detect vendor mixups or errors.

The Commissioner agrees with this statement and notes that labeling is required to be examined or tested for these deficiencies by § 211.122 before being issued for use.

332. Several comments suggested substituting the word "significant" for "any" in § 211.125(c) because the proposed wording would require an evaluation if there was a discrepancy of only one label.

The Commissioner believes that these objections are suitably resolved by revising the wording to allow deviations within narrow preset limits.

333. Some comments on § 211.125(c) said that in situations where there is unique labeling, unique labeling equipment, single-product packaging lines, and other adequate quality control procedures, labeling reconciliation is unnecessarily expensive and time consuming and does not preclude misbranding.

The Commissioner believes that label reconciliation is important because labeling mixups are one of the major reasons for recalls. Regardless of the sophistication of the labeling system used, lack of labeling reconciliation would be a weak link in the total control of labels from their receipt to their use.

334. One comment on § 211.125(c) argued that the institution of elaborate control procedures for a half-dozen individually typed labels is more an annoyance than a hardship.

It is difficult for the Commissioner to believe that the reconciliation requirement, when applied to six labels, is either an annoyance or a hardship.

335. One comment on § 211.125(c) said there is little reason to reconcile shipping container labeling.

The Commissioner does not agree with this statement. Misapplication of labeled cartons can cause a recipient to wonder which is correct—the carton label or the container label. Furthermore, the Commissioner believes that such reconciliation is not overly burdensome or costly and is a current practice in the industry.

336. Several comments on § 211.125(d) suggested that recoding of excess labeling be permitted in lieu of destruction.

The Commissioner rejects these suggestions. The possibility of error outweighs any benefit that would be derived from salvaging labeling with obsolete lot numbers. The agency's experience indicates that the majority of drug firms destroy excess labeling that bears lot or control numbers.

337. Some comments suggested adding wording to § 211.125(d) to denote when destruction of labeling should take place.

The Commissioner believes that excess labeling bearing lot or control numbers should be destroyed as soon as possible after labeling of the batch and before labeling of any subsequent batches. In view of the requirements in § 211.130(d), however, the Commissioner does not consider it necessary to set forth exactly when destruction must take place.

338. One comment on § 211.125(e) argued that cut labels and labeling should not be returned to stock because of the inherent danger of mixup, but rather should be counted and destroyed.

The Commissioner finds that this suggestion would be too restrictive for those manufacturers who use cut labels. He believes that with proper control, cut labels can be used without the occurrence of mixups.

339. Some comments suggested incorporating proposed § 211.125(f) into § 211.125(c) where much of the intent is already covered.

The Commissioner agrees with these comments and has revised the final regulations accordingly.

340. Several comments suggested deletion of the words "in detail" from proposed § 211.125(g) (now § 211.125(f)) because they are superfluous and potentially misleading. One comment said a standard of reasonableness should be employed for the intended purpose.

The Commissioner notes that the words "in detail" could be construed as requiring inclusion of minute detail. Therefore, the Commissioner is inserting the word "sufficient" before the word "detail."

341. One comment suggested deletion of proposed § 211.125(g) (now § 211.125(f)) because it is unnecessarily repititious of § 211.125(c).

The Commissioner does not agree that this paragraph is redundant. Section 211.125(c) requires the employment of certain procedures, whereas paragraph (f) requires those procedures to be in writing and to be followed.

PACKAGING AND LABELING OPERATIONS

342. Comments on § 211.130(a) suggested that mixups and contamination can be prevented by spatial separation as well as by physical separation as required in § 211.130(a).

In using the word "physical," the Commissioner intended that spatial separation be considered as a type of physical separation. To preclude misinterpretation, he is revising this paragraph to clarify that spatial separation can be an acceptable method of separation.

343. One comment suggested insertion of the phrase "the probability of" between "of" and "mixups" in § 211.130(a).

The Commissioner rejects this suggestion because he believes it would make the paragraph confusing.

344. One comment suggested that the word "container" be inserted between the words "product" and "with" in § 211.130(b).

The Commissioner finds that it is not the purpose of CGMP regulations to specify all appropriate labeling, containers, or shipping cartons that should be required to bear a lot or control number. It is sufficient for these regulations to require that the manufacturing history of the drug product can be determined from a lot or control number.

345. One comment on § 211.130(c) suggested that the word "batch" be replaced by the word "appropriate," because in large operations, records may be kept according to production runs, which may include a number of batches.

The Commissioner rejects a substitution for the word "batch." It is the intent of the Commissioner that the batch production and control records be complete. Because the examination of labeling and packaging materials before use is a function of the production of a batch, the batch record would not be complete without this information.

346. One comment said certain packaging materials, such as corrugated paper, should not come under the requirements of § 211.130(c).

The nature and extent of the examination of packaging materials, including corrugated paper, will vary; but, nonetheless, an examination of some kind must be performed to assure that the material is suitable for its intended use. Packaging materials often provide product protection, and the characteristics of packaging materials must be taken into account.

347. Some comments in § 211.130(d) said it is not necessary to clear a line of packaging materials such as bottles, cotton, caps, circulars, or other general packaging materials if that packaging material is to be used on subsequent batches of the identical drug product to be packaged in the identical package unit. Several comments regarding proposed § 211.130(e) argued that packaging and labeling material common to the succeeding production run not be removed from the finishing area after the completion of operations and prior to the next run.

The Commissioner does not intend to require that packaging materials common to consecutive batches of a drug product be removed between such batches. Revision of § 211.130(d) has clarified the requirements for removal of previously used packaging and labeling materials. Further, the Commissioner finds that the requirements of paragraph (e) are adequately covered in paragraph (d), and therefore proposed § 211.130(e) is deleted in the final regulation.

DRUG PRODUCT INSPECTION

348. Several comments on § 211.134 argued that the requirement for assuring that every container and package has the correct label would require 100 percent examination of the drug product during or after finishing operations.

It is not the intent of the Commissioner to require 100-percent inspection of the drug product either during or after finishing operations. To clarify this section the Commissioner is deleting the word "every" in § 211.134(a). He is also replacing the word "assure" with the phrase "provide assurance." The Commissioner notes that this section as written in the final regulation requires a high level of confidence, but does not necessarily require 100-percent inspection. The Commissioner encourages 100-percent inspection by either visual or automatic methods because drug product labeling mixups have been a major cause of recalls. Although 100-percent inspection might not provide absolute assurance, it would provide a higher level of confidence that every container and package in a lot has the correct label.

349. A comment said the parenthetical phrase "(visually, mechanically or electronically)" should be inserted after the word "examined" in line 2 of § 211.134(a).

The Commissioner notes that § 211.68(a) permits the use of precision automatic, mechanical, or electronic equipment in all phases of drug product manufacture, processing, packing, and holding. Therefore, there is no reason to repeat this statement in each section where such equipment might be used.

350. A comment argued that the wording of § 211.134(b) implies that the "representative sample" should be taken from sealed and palletized shipping cases.

If shipping containers are labeled to contain a particular drug product, then it is the Commissioner's intention that individual shipping containers be examined to assure that the correct drug product is in the appropriate containers. A lot or batch does not necessarily have to be sampled after it has been palletized because, generally speaking, palletizing is not considered as part of the finishing operation referred to in § 211.134(b).

351. One comment on § 211.134(b) recommended that, in addition to visual examination, an identity test be required on the drug product if the firm packs physically similar drug products.

The Commissioner does not agree with the suggestion that this paragraph contain provisions for identity testing if the firm packs drug products that are physically similar. Section 211.120 (d) and (e) provides for the clearance of packaging and labeling areas before use. Section 211.165 provides for physically testing the drug product after packaging. The purpose of this paragraph is to provide assurance that the correct labeling has been applied.

352. One comment said the results of the examination need not be recorded on the batch production or control records if they are recorded elsewhere.

The Commissioner rejects this comment. It is important that the batch production and control records be complete regarding the history of the batch, including the results of examination of the drug product after packaging and labeling. It is not essential, however, that all information that belongs in the batch production or control record necessarily be on one piece of paper.

EXPIRATION DATING

353. Many commented on proposed § 211.137, which would require expiration dating for all drug products. A number of comments agreed that expiration dating was appropriate for certain drug products, for example, those subject to fairly short-term deterioration, but objected strongly to requiring expiration dating for all drug products and concluded that a requirement for expiration dating of all drug products would not benefit the consumer. A few comments objected specifically to expiration dating for over-the-counter drug products or drug products whose active ingredient is known to be extremely stable and that have, for all practical purposes, an unlimited shelf life. Examples given of such stable products include naturally occurring chemical compounds that are mined from the earth, refined, packaged, and sold for medical purposes. A number of comments from consumers were very strongly in favor of expiration dating for all drug products.

The Commissioner notes a trend toward voluntary dating of many perishable consumer products, particularly food and drug products. He believes that this trend has been generated in large part by consumers and consumer organizations who have expressed great interest in expiration dating of such products and by manufacturers responding to this interest.

The pharmaceutical industry has been aware for a number of years that FDA believes it is in the public interest for manufacturers to provide information regarding the stability of its drug products. In the preamble to amendments to CGMP regulations published in the FEDERAL REGISTER of January 15, 1971 (36 FR 601), the Commissioner announced his conclusion that the interests of consumers must be served by the establishment of valid expiration dates for drug products. At the time, the Commissioner expanded basic requirements in the CGMP regulations for stability testing to allow time for manufacturers to accumulate data to support expiration dating.

In the preamble to the February 13, 1976 proposal, the background regarding expiration dating was discussed at length. The Commissioner pointed out that a number of drug manufacturers were already voluntarily providing expiration dates for their products; many products such as antibiotics, biologics, and drugs liable to deterioration were already required to bear expiration dates; and the latest editions of the United States Pharmacopeia (U.S.P.) and National Formulary (N.F.) require expiration dating for all products subject to compendial requirements.

The Commissioner does not believe that expiration dating of drug products places an undue burden on drug manufacturers. Those who have been complying with the 1971 CGMP requirement for stability testing will, for most drug products, already have data available on which to base a suitable expiration date. When new products are being manufactured or when stability data are not otherwise available, the new CGMP regulations in § 211.166 clearly provide for a tentative expiration date based on several factors, including accelerated studies.

Although no sound arguments were presented to the Commissioner that expiration dating of most drug products would not benefit the consumer, the Commissioner has tentatively concluded that it may not be advantageous to consumers, in consideration of cost vs. benefit, to require expiration dating for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years, as supported by appropriate stability data. Therefore, the Commissioner has elected to delay implementation of the requirement for expiration dating for these products and is proposing elsewhere in this issue of the FEDERAL REGISTER to exempt these products from expiration dating. The Commissioner expects that types of products that would be affected by this exemption would include a number of medicated shampoos, topical lotions, creams and ointments, medicated toothpaste, and rubbing alcohol. The Commissioner advises that until comments submitted in response to this proposal for exemption can be carefully evaluated and a decision made as to the suitability of such an exemption, the Food and Drug Administration will not enforce the expiration dating requirements of this section for the type of products that he is proposing to exempt. The Commissioner believes it is significant that the types of products he proposes to exempt from expiration dating are acceptable for frequent and often prolonged use without dosage limitation, and typically the contents of the retail package are used in a relatively short period of time. The Commissioner also notes that few of these products currently bear expiration dating, and he is not yet persuaded in consideration of the comments that the costs involved in requiring expiration dating for these products can be justified on the basis of the information available to him at this time.

354. After reviewing the comments from individual consumers, the Commissioner believes that some private citizens misunderstood the applicability of expiration dating for all drug products and believed that the requirement for expiration dating will extend to drugs dispensed by a pharmacist on the written order or prescription of a physician. Section 503 of the act specifies the kind of information that must be supplied by the pharmacist to the consumer regarding the prescription drug. While the Commissioner has found that a number of pharmacists voluntarily indicate an expiration date on the prescription drug container given to the patient, such transfer of information is not required by law and, until the subject regulations are in effect, such expiration information will not be available to pharmacists for all prescription drug products. The Congress is now considering bills to amend the act to provide for expiration dating on all prescription drugs dispensed to consumers. The agency supports such legislative proposals.

355. Several comments opposed the inclusion of expiration dating in CGMP regulations on the ground that the misbranding section of the act, section 502 and, in particular paragraph (h) of that section, provides for expiration dating to the exclusion of the adulteration section, section 501, especially paragraph (a)(2)(B) relating to CGMP regulations. Further comment was that regulations issued under section 502(h) of the act are subject to the administrative provisions of section 701(e) of the act, which includes provisions for a public hearing if requested.

The Commissioner rejects these arguments. No paragraph of section 502 of the act expressly refers to expiration dating. Paragraph (h) of section 502 describes products liable to deterioration and the packaging and labeling that may be necessary to minimize such deterioration. Although expiration dating might be considered implicit in this paragraph, the Commissioner does not find any basis for concluding that only labeling referred to in paragraph (h) of section 502 of the act can be required to carry dated labeling, or that the only statutory authority for FDA to enforce expiration dating is under this paragraph. He notes, for example, that where expiration dating is required by an official compendium such as U.S.P. or N.F., FDA has authority to enforce this requirement under paragraph (g) of section 502. Section 502(a)(2)(B) of the act clearly provides to FDA broad authority to assure the quality, purity, identity, and strength of drug products at least through the time of dispensing to patients or sale to consumers. The determination of stability of a drug product and the reporting of this information through an appropriate expiration date are an integral part of the assurance of drug quality.

356. A number of comments opposed expiration dating specifically for over-the-counter drug products. The arguments were primarily that: (1) Many OTC drugs are extremely stable and that expiration dating is of little value for products whose stability can be measured in terms of many years; and (2) that any required expiration dating for OTC drug products should coincide with final regulations developed under the current OTC drug review process. In the latter case, comments expressed concern that labeling changes required by expiration dating and probable labeling changes and formulation changes required at a later date under final OTC drug review regulations would be an unfair burden on manufacturers.

The Commissioner notes that he has already discussed in paragraph 353, the interim enforcement policy regarding human OTC drug products that are stable and marketed without dosage limitations. But he sees no valid reason for separating requirements for drug expiration dating for prescription drug products and most OTC drug products. The Commission-

er recognizes that firms should ordinarily be free to select any expiration date that falls within the documented stability period, and the regulations permit manufacturers to use any expiration date that is supported by appropriate stability data. Even if a manufacturer knows that the active ingredient of its drug product is stable for 20 or 30 years, without expiration dating it is unlikely that the user of the drug product is going to know this information. The Commissioner believes that expiration dating will be more than marginally beneficial to consumers even for drugs that are unusually stable. First, it will reinforce pharmacist and consumer confidence in the product, and thus will avoid unnecessary disposal and replacement of old but not outdated drug products. Second, it will prevent confusion for drug dispensers and probably consumers that would naturally occur in a system where some, but not all, products carried expiration dating.

The Commissioner sees no undue burden on manufacturers in requiring expiration dating of over-the-counter drug products prior to final OTC drug monographs. The Commissioner notes that a wide variety of methods for expiration dating of drug products are available and that many of these methods do not require changes or reprinting of labels. If formulation changes are required as a result of a final OTC drug monograph, the regulations in § 211.166 provide for development of tentative expiration dates. Since the expert OTC advisory review panels will not be considering the expiration dating of OTC drugs as a routine matter in their deliberations, the Commissioner sees no valid reason for further delaying expiration dating for most OTC drug products.

357. Comment was received from the American Homeopathic Medical Association, representing the views of various aspects of homeopathic medicine, including manufacturers of homeopathic drug products, specifically requesting an exemption from the proposed requirement of expiration dating and related stability testing for their products. The basis for the request is that homeopathic drugs characteristically contain such extremely small quantities of active ingredients that the finished product cannot be tested by usual analytical methods. Further, because of the theory behind homeopathic medicine, regard for determining the specific level of active ingredient and the normal measures of stability are inappropriate.

The Commissioner notes that homeopathic medicine and drugs used for homeotherapeutics are unique and differ substantially from other forms of pharmaceutical products. Previously, the Commissioner has exempted homeopathic drugs from the Over-the-Counter Drug Review (see the FEDERAL REGISTER of May 11, 1972 (37 FR 9464)). Further, homeopathic drugs were excluded from review under the NAS/NRC Drug Efficacy Study Review (DESI) and distributors of homeopathic drugs have not been required to list such drugs under the Drug Listing provision of the act. (Manufacturers, however, are required to register as drug establishments.)

Because of the unique nature of homeopathic drugs, the Commissioner has reconsidered the value of stability testing and expiration dating for this small class of drug products and concludes the need for expiration dating and complete stability testing, as proposed, are unnecessary in this group. The imprecise nature of determining extremely low levels of active ingredients for each of a large number of attenuations (dilutions) that may be prepared for each drug substance, and the fact that factors such as potency, absorption, bioavailability and other measures of effectiveness do not appear to be applicable to homeopathic drugs, have convinced the Commissioner that requiring an expiration date for such products would be a burdensome requirement that would not result in any added assurance of drug quality to the user.

Certain provisions of the proposed stability testing requirements, especially those relating to determining an expiration date, are also inappropriate. On the other hand, some stability information, such as the compatibility of ingredients based on testing or examination and marketing experience, is necessary for this class of drug products. The final regulations are amended in § 211.166 by modifying the stability testing requirements for homeopathic drugs.

358. Several comments expressed concern whether small labels of some drug products could accommodate an expiration date. Several other comments raised questions regarding the applicability of the expiration dating to their own specific small-sized products. In one instance, a manufacturer indicated that it would be required to purchase new equipment in order to apply the expiration date to the crimp of the tube for a medicated cream. In another instance a manufacturer indicated that its products were individually packaged in a way that the units stay with an outer packaging until all the individual units are used; it inquired whether each individually wrapped unit was required to bear an expiration date.

The problem of certain labels being too small to accommodate statements required by FDA has been raised many times in the past. A specific regulation has been issued to address this problem (see 21 CFR 201.100(b)(6)). Currently, a substantial number of drug products are packaged in a wide variety of containers, with a substantial range of label sizes, yet these often are marked with an expiration date. For example, a number of drug products for use in hospitals are being packaged in "unit dosage" containers that bear all the required information as well as an expiration date. The Commissioner believes that technology and the availability of different methods of placing the expiration date on the immediate container are now at a state where it is reasonable to expect that any drug product package can accommodate an expiration date. There will still be individual situations where it will be necessary to determine whether a particular packaging constitutes a protective or convenience wrap and therefore is not required to bear full labeling, or constitutes the immediate container, and therefore should bear all required labeling including an expiration date. If a packager of drugs has any question regarding this matter, FDA will render an opinion upon request from the packager. The request should be sent to Advisory Opinions Branch (HFD-35), Bureau of Drugs, Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857, and should include full information regarding the packaging as well as examples of the packaging materials and labeling.

359. One comment expressed concern that the presence of an expiration date on small containers may serve only to detract from the conspicuousness of other information, including warnings and dosage recommendations.

The Commissioner rejects this argument. The practicality and advisability of requiring specific items of information on the immediate container must always be evaluated in light of whether it might compromise or obliterate the value of entire labeling of the immediate container. The Commissioner finds that a uniformly short statement of an expiration date will not interfere with the conspicuousness of other required information. Further, the Commissioner finds that there is no practical alternative to convey expiration dating information other than to place it on the immediate container.

360. Several comments were received regarding the need for expiration dating of cylinders of compressed medical gases. One comment noted that expiration dating of these drug products would not benefit the patient.

The value of imparting stability information to consumers or to those who dispense drug products has been discussed previously. As stated earlier, the Commissioner cannot agree that

expiration dating of most drug products would not benefit the user, whether or not the patient is personally aware of the expiration date. The Commissioner sees no justification at this time for exempting compressed medical gases from the requirement of expiration dating.

361. One comment objected to expiration dating of OTC drug products such as absorbent cotton, gauze bandages, eye pads, triangular bandages, cotton balls, and surgical gauze. The comment was that these products last indefinitely and that some of these products, dating back from World War I, are being sold and are perfectly satisfactory. Another comment expressed an opinion that, with regard to expiration dating, all attention seems to be focused on the stability of the drug formulation. The comment concluded that other factors, such as packaging and storage conditions, must contribute to the determination of an appropriate expiration date.

The Commissioner notes that these comments, apparently from opposite points of view, illustrate his concern that all persons should understand that there are other factors to be considered besides the stability of a specific active ingredient in determining a suitable expiration date; these include the stability of the inactive ingredients, the interaction of active and inactive ingredients, the manufacturing process, the dosage form, the container closure system, the conditions under which the drug product is shipped, stored, and handled by wholesalers and retailers, and the length of time between initial manufacture and final use. For example, the period of time in which the sterility of a drug product can be assured may be substantially less than the inherent stability of the active ingredient. Thus, the expiration date for a sterile drug product may have a different basis than that for a nonsterile drug product of the same active ingredient. Container closure systems or tablet coatings, for example, may increase or decrease the shelf life of the drug product. Therefore, as mentioned earlier, a number of factors must be taken into account in considering a drug product's stability. The Commissioner also notes that articles such as cotton, gauze, bandages, and eye pads are now considered devices and will be handled under the Medical Device Amendments of 1976 and are no longer subject to these CGMP regulations. Expiration dating for certain kinds of medical devices is now under consideration by FDA.

362. Several comments recommended that FDA consider requiring that expiration dates fall within the same 1 or 2 months of every calendar year. For example, it was suggested that all drug products bear an expiration date that would end in January (or January and July) of the calendar year for which the manufacture has established a date of expiration. The comments indicated that such a procedure would not interfere with establishing dating periods in multiples of 6 months or 1 year and would allow persons who need to make inventories of drug product stocks to easily survey such stocks for outdated drug products.

While the Commissioner sees merit in a provision that would allow all outdated products to be readily identified and removed only once or twice annually, he believes that such a requirement would not be justified at this time. Manufacturers may use an expiration dating scheme that will provide an appropriate uniform expiration cutoff date to facilitate inventory control over outdated drug products in the channels of distribution. The Commissioner will further consider the utility and currency of such a practice and whether future regulations would be appropriate.

363. Several comments spoke to the issue of a maximum expiration date, such as 5 years, about which the Commissioner had requested information and data that would establish whether any fixed maximum arbitrary date is in the best interest of the consumer. Most comments expressed strong opposition to a fixed maximum expiration date. One such comment expressed the view that a maximum expiration dating period would discourage development of improved stability formulations and packaging. Another comment, which supposed that a 5-year dating period is generally acceptable to the pharmaceutical industry, recommended that such maximum expiration dating period be adopted with provisions that the time period could be extended on the basis of adequate data. This same comment suggested that an advantage of a maximum expiration date would be to limit the length of time the drug product is not under the control of the manufacturer. The time limit would reduce the possibility of damage by environmental agents, adverse changes in packaging materials, and obsolete labeling.

The Commissioner advises that his request, appearing in the preamble to the February 13, 1976, proposal, for information and data showing that the establishment of an arbitrary date (5 years or any other time period) is in the interest of the consumer, resulted in generally unfavorable comments and no information or data to support public interest in a maximum expiration date, either by consumers or industry. Therefore, the Commissioner concludes that he has insufficient information at this time to find that setting a specific maximum expiration dating period is suitable or desirable for drug products.

364. A number of comments objected to the word "statistically" or the phrase "statistically validated" used in § 211.137(a) in reference to the use of a "statistically validated expiration date determined by appropriate stability test." The arguments were that for some drug products the expiration period is established based on characteristics or attributes (e.g., color of tablets) which are subjective and not amenable to statistical analysis. For new drug products, stability data may be quite limited and there are insufficient data for meaningful statistical analysis. In such cases, a manufacturer stated, expiration dates are conservatively assigned. Another comment indicated that statistical validation is duplicative and open to dispute in interpretation. Several comments indicated that they were unsure as to what was required for statistical validation. Another comment explained that expiration dates are currently derived from actual stability tests involving the use of accelerated stability tests. The comments said that such accelerated stability tests do not need to be statistically validated as long as there is adequate justification for use of the conversion factors that relate the conditions of the study to labeled conditions. Another comment said the use of statistics to derive an expiration date is only one of many ways that a valid expiration date can be obtained. Most comments on this paragraph suggested deletion of the word "statistically" or the phrase "statistically validated." Several comments suggested revised wording to incorporate the phrases "appropriate expiration date" or "statistically or mathematically validated date."

The Commissioner finds that § 211.166 on stability testing, which has been modified in the final regulation, contains the requirements that are the basis for establishing an expiration date. An appropriate expiration date, determined in conformance with the provision of § 211.166, will meet the requirements of § 211.137; therefore, the statistical validation requirement is not necessary to § 211.137. The final regulation has been revised to clarify this issue.

365. Several comments suggested that the 6-month delayed effective date proposed by the Commissioner was insufficient to allow accumulation of the necessary data to determine appropriate expiration dates. Several firms suggested a 3-year delayed effective date for this requirement; another suggested a 2-year delayed effective date. Another firm indicated that it was common industry practice to allow a 3- to 5-percent seasonal return and

redistribution of OTC products. This firm requested provisions in the regulations to allow for such redistribution from inventory of drug products that do not bear expiration dates.

The Commissioner believes that the industry has been on notice concerning expiration dating for a number of years and should have data developed under the basic stability requirements that have been in effect since 1963. Because of such general widespread knowledge and the "state of the art" regarding expiration dating, a 6-month delayed effective date in adopting this requirement should be an adequate transitional period in which to establish expiration dating procedures. To allow distribution (or redistribution) of labeled stocks, however, the expiration dating required by these regulations shall not apply to stocks of drug products that have been labeled prior to the effective date of these regulations.

366. One comment said § 211.137(a) and § 211.166 are inconsistent in that § 211.166 permits the use of tentative expiration dates based on accelerated studies combined with basic stability information.

In revising § 211.137 in response to other comments, the Commissioner has included a specific reference in § 211.137(a) to § 211.166. As codified, § 211.137 clearly refers to the use of appropriate stability tests and stability studies described in § 211.166. Thus, the Commissioner now sees no possible contradiction in these two sections.

367. Several comments objected to the introductory phrase "to assure" in § 211.137(a). The comments were that the phrase is an impossible restraint and that an expiration date cannot "assure" that a drug meets identity, strength, quality, and purity standards.

The Commissioner cannot agree with these comments. In common usage, the word "assure" implies a confidence that can reasonably be expected. The purpose of expiration dating is to inform users of the drug product that they can reliably expect that the product meets the professed standards of identity, strength, quality, and purity at the time of actual use.

368. One comment suggested that § 211.137(a) should provide that adherence to dating periods in approved new drug applications (NDA's) would constitute compliance with this section.

The Commissioner believes that it is unnecessary for the regulations to specify that adherence to dating periods in approved NDA's would constitute compliance with § 211.137(a). Dating periods for products covered by approved NDA's are based on stability data submitted as part of the NDA's. These stability data have generally come from testing programs that fulfill the requirements of § 211.166. If so, then such data also fulfill the requirements of § 211.137(a). If not, the NDA probably was approved many years ago and new testing, using more sophisticated techniques, is appropriate. For such products, the new CGMP requirements should not be and are not met by the approved NDA, and testing complying with § 211.166 is required.

369. Several comments recommended that § 211.137(a) be revised to include a statement to the effect that a drug product would not be required to bear an expiration date if it is determined on the basis of appropriate stability tests and on distribution and consumer usage patterns that the product will be consumed before significant deterioration occurs.

The Commissioner notes that he has considered stability and consumer usage patterns in establishing the interim enforcement policy discussed in paragraph 353 of this preamble. But he does not agree that the suggested revision would be suitable for all drug products, namely, prescription drug products and OTC drug products with dosage limitations. Such provision would ignore a basic principle of expiration dating—that the manufacturer furnish information to reduce the chances of outdated drug products being consumed. The Commissioner does not think it is realistic to assume that every unit of a drug product will be consumed within a specific period of time, notwithstanding the considerable experience many manufacturers have regarding distribution and consumer use patterns. Information regarding distribution and consumer use patterns, however, will serve to assist manufacturers to estimate the quantity and duration of stability information that would be worth developing; that is, if a supplier is confident that more than 90 percent of a product is out of the distribution chain in 3 years, the supplier may not wish to incur the expense of establishing a 5-year stability for the product and labeling it with a 5-year expiration date.

370. Some comments said proposed § 211.137(b) was somewhat redundant when viewed in light of paragraphs (a), (c), and (e) of this section. The comments also recommended that if paragraph (b) were retained, the references to appropriate statistical analysis should be deleted. One comment recommended that paragraph (b) be revised to include mathematical use as well as statistical analysis. Another comment stated that the phrase "readily available data" should be further defined.

The Commissioner finds that with minor editorial differences the essential provisions of this paragraph also appear elsewhere in § 211.137. Therefore, he has decided that the proposed § 211.137(b) will be deleted.

371. A number of comments objected to the provisions of proposed § 211.137(c) (recodified as § 211.137(b) in the final regulation), specifically suggesting that drug products suitable for storage at room temperature not be required to bear appropriate storage conditions on the labeling.

The intent of proposed § 211.137(c) is to relate expiration dates to any storage conditions determined by the manufacturer of a drug product to be important and thus stated in the labeling. A manufacturer may conclude that the expected normal handling conditions of the drug product do not require specific labeling instructions, or the manufacturer may elect to include any special handling or storage instructions to preserve the product's stability. An editorial change in the final regulation clarifies that storage instructions are not required in every instance.

372. One comment suggested that when proposed § 211.137 (d) and (e) are read in conjunction with § 201.17, it is obvious that expiration dates are required only for labeling described in § 201.17 and therefore package inserts are excluded. The comments suggested that the language in the section be revised to specifically exclude package inserts from a requirement to bear expiration dates.

The Commissioner sees no reason that the regulations exclude, by name, package inserts from a requirement to bear an expiration date. The regulations in § 201.17 and, by reference, in § 211.137, clearly specify which labeling is required to bear expiration information. To designate, by name, the labeling not required to bear such information is impractical because it includes more than the package insert and it is unnecessary and potentially confusing.

373. One comment recommended adding a new paragraph in § 211.137, which would provide that in the case of licensed biological drug products, an expiration date, if applicable, either shall be determined by regulations specific for the product involved, or shall constitute part of the product license.

The Commissioner cannot adopt this suggestion. A biological drug product should bear an expiration date even if one has not been specifically established for that product either in regulations for the drug product involved or as part of the product license.

XIII. Holding and Distribution

Warehousing Procedures

374. A comment said § 211.142 should not require rigid physical separation

of quarantined drug products before release by the quality control unit.

The Commissioner did not intend, nor does this section state, that rigid physical separation of quarantined drug products is necessarily required before release by the quality control unit. The degree of separation necessary would be dependent on other steps taken to assure that quarantined drug products are not used prematurely. For example, proper paper control or computer systems could offset the need for physical separation.

375. One comment recommended that the words "of temperature, humidity, and light" be deleted from proposed § 211.142(b) because humidity and light are not controllable in a normally operated warehouse.

The Commissioner disagrees that humidity and light cannot be controlled in a warehouse. However, he notes the regulation does not require these factors to be controlled unless the identity, strength, quality, and purity of the drug products would be affected. The Commissioner believes that the regulation as written clearly requires that all drug products be stored under conditions that are consistent with maintaining the stability of the product. The conditions of storage will vary according to the particular product; hence the use of the word "appropriate" in this paragraph. At the very least, storage conditions should always be such that there are no extremes. If the conditions of temperature, humidity, and light are extreme enough, almost any drug product would be affected.

DISTRIBUTION PROCEDURES

376. A comment on § 211.150(b) said a requirement of lot number traceability is inappropriate and unnecessary when applied to the great majority of drug products for which the incidence of recall is extremely low.

The Commissioner notes that this requirement is already in the existing CGMP regulations and is "current practice." He does not have information to support a contention that certain drugs are less likely than others to be recalled. Therefore, the Commissioner cannot accept this comment.

377. One comment said § 211.150(b) should be deleted and § 211.150(a) recodified into the introductory text of § 211.150 because the act does not provide for recalls and because the objective of § 211.150(b) is substantially covered under § 211.196.

The Commissioner does not believe that these two sections are redundant. Section 211.196 requires that distribution records be kept containing certain information. Section 211.150(b) requires that distribution recordkeeping systems include the capability of identifying the distribution of any specific lot so that a recall may be facilitated. The Commissioner also does not believe that § 211.150 mandates recalls. Section 211.150 recognizes that it is a current good manufacturing practice within the pharmaceutical industry to have appropriate systems to carry out the occasional recalls or withdrawals from distribution of drug products. These actions are generally voluntarily undertaken by manufacturers. Because such mechanisms are a current and good practice, the Commissioner has legal authority under section 501(a)(2)(B) of the act to require them for all drug suppliers. The question of FDA-requested recalls is subject to separate regulations published in the FEDERAL REGISTER of June 16, 1978 (43 FR 26202).

378. One comment said the distribution records maintained by compressed medical gas suppliers are adequate to accomplish § 211.150(b), but the requirement of § 211.196 calling for the lot number on distribution records is unnecessary. Further comment said compressed medical gas lots are distributed in a very small geographical area and to a very limited number of accounts, and recall is a much simpler problem for medical gases than for the widely distributed multiple-unit lot drugs.

The Commissioner fails to understand how the intent of § 211.150(b) can be accomplished without meeting the requirements of § 211.196, and no such information was provided in the comment. The intent of § 211.150(b) is that a firm be able to determine how much of a given lot, if any, was shipped to each consignee and on what date. The Commissioner does not believe that compressed medical gases should be exempt from this requirement, because they are potent drugs, and distribution accountability is of as much importance in case of recall of them as for any other drug.

379. One comment said the phrase "and appropriate" should be inserted after the word "possible" at the end of the proposed § 211.150(a).

The Commissioner agrees with this comment. In addition, the wording in the final regulation for this section has been revised to make it consistent with § 211.86 as it pertains to the first-in, first-out concept. The final regulation provides that deviation from the first-in, first-out requirement is permitted if such deviation is temporary and appropriate.

XIV. LABORATORY CONTROLS

GENERAL REQUIREMENTS

380. One comment recommended that the word "justified" in the last sentence of proposed § 211.160(a) be changed to "explained."

It is not enough, in the Commissioner's view, that a deviation from standards be explained. The deviation must be supported by sufficient reason to show that it is needed and has no adverse impact on the drug product. Therefore, the recommendation is not adopted.

381. A comment requested a definition for "specification" in § 211.160(a) so that it would describe a general category rather than a single document, and specifications could be prepared as separate documents for separate areas.

The Commissioner does not believe that, as written, the regulation requires that all specifications for all areas, such as sampling and testing, be a part of the same document. The word is used here in a general sense rather than as a reference to a single document.

382. One comment said §211.160(a) is ambiguous because it does not define requirements. The comment asked whether documentation is needed showing completion of requirements.

The Commissioner advises that § 211.160(a) is intended to refer to requirements that appear throughout Subpart I—Laboratory Controls. A wording change in the final regulation clarifies this intent. With regard to the respondent's question concerning documentation, the Commissoner also advises that § 211.194(a) contains a requirement for documentation.

383. Two comments proposed deleting the references in § 211.160(b) to sampling plans and testing procedures and merely requiring documentation of what was done. The reasons for proposing this deletion were not made clear.

The Commissioner believes that adequate controls include not only standards and specifications but also the sampling plans and testing procedures to determine acceptability. These plans and procedures must be determined in advance of implementation—otherwise no systematic or comprehensive evaluation of the acceptability of materials and finished products can be assured.

384. A comment suggested inserting the phrase "or a reference to" after the word "description" in the sentence referring to descriptions of sampling plans and testing procedures in specifications.

The Commissioner interprets the comment's concern to relate to the extent of the description required for the sampling and testing procedures used when these are set forth in detail in other documents. The description depends on a number of factors, but certainly could include references to authoritative procedures such as the official compendia. The Commissioner does not believe the language need be modified, however, because he believes the word "description" provides suffi-

cient latitude for the use of references, where appropriate.

385. A comment said the requirement in § 211.160(b)(4), providing for remedial action in the event equipment calibration checks showed problems, is impractical because a course of action for each possible event could not be written. Instead, it suggested the paragraph read "* * * provisions for investigations to determine the necessary action."

The Commissioner believes that broad instructions can be developed for remedial action. The regulations in this section do not specify the detail in which such provisions must be developed. In some cases, these instructions could provide principally for an investigation to determine the cause of a problem. In other instances, for example, where a problem can be expected to occur regularly, detailed instructions may be practical.

386. Several comments felt that inclusion in § 211.160(b) of components, drug products, and in-process materials with containers, closures, and labeling was irrational.

Controls throughout this section are only required as appropriate. It is not the Commissioner's intent to require inappropriate standards and testing. The substance, extent, and complexity of controls will vary with components, containers, closures, and labeling, but suitable specifications, standards, sampling plans, and test procedures are necessary for each.

TESTING AND RELEASE FOR DISTRIBUTION

387. Comments on § 211.165(a) pointed out that potency assays are often tests for identity, and therefore the reference to identity tests should be removed.

The Commissioner does not believe that every potency assay would also serve as an identity test. In those cases where one test can suffice for both purposes, the wording of this paragraph would accept a single test.

388. One comment asked for an exemption from the prerelease sterility and pyrogen testing requirements of § 211.165(a) of shortlived radioactive materials.

The Commissioner recognizes that for short-lived radiopharmaceuticals it is not possible to obtain results of these tests before the active material degrades below a useful level. Therefore, the final regulations in § 211.165(a) permit release of those specific batches that are undergoing sterility and/or pyrogen testing, prior to completion of those tests, provided such testing is completed as soon as possible.

389. Several comments requested clarification of § 211.165(a) to determine whether it means that potency assays have to be done at both the bulk and packaged drug product phases, or only at the bulk phase.

The Commissioner purposely worded this paragraph so that manufacturers could choose to do potency assays at either phase, but certainly before release for marketing. There is no intent, once the product is in its finished dosage form, to require potency testing of more than one phase by the manufacturer. The Commissioner believes the paragraph is clear in this regard.

390. Two comments maintained that identification and potency testing of each active ingredient in a combination product or in small batches of OTC products constitutes a highly inflationary procedure.

The Commissioner believes that testing to assure that a product is what it purports to be is basic to a quality control program for any drug product. Further, he notes that the substance of this requirement has been in the CGMP regulations since 1963 and is generally a current industry practice. Therefore, he finds that such a basic procedure should not have a significant inflationary impact or that this cost is unjustified in view of the assurances the procedure gives the consumer. The comments are rejected.

391. A comment suggested limiting § 211.165(c) to sampling by deleting references to testing, on the grounds that § 211.160 adequately covers the requirements for written testing plans.

The Commissioner notes that § 211.160 has general objectives regarding sampling and testing of drug products. Requirements for release of drug products are more specifically described in § 211.165. Therefore, the Commissioner declines to accept this comment.

392. Several comments objected to or redefined the concepts of acceptable quality level (AQL) and unacceptable quality level (UQL) used in establishing acceptance criteria and statistical quality control criteria as proposed in § 211.165(d). The comments pointed out that the concepts of AQL and UQL are not uniformly interpreted, and their use in establishing acceptance criteria and statistical quality control criteria is not uniformly applied. Comments expressed concern that the concepts of AQL and UQL as acceptance criteria are premature and not currently a part of good manufacturing practice. One comment suggested that these proposed CGMP regulations would require extensive changes in testing procedures, facilities, and use of manpower. Several objections were raised relative to the "usually 95 percent" level of high probability of acceptance. Respondents pointed out that this figure might be applicable for some pharmaceutical dosage forms, but would be too high for others.

As anticipated by the Commissioner, the concepts of AQL and UQL in establishing acceptance and statistical quality proved quite controversial. From an analysis of the comments, the Commissioner believes that it is impractical at this time to establish a uniform system of AQL and UQL as proposed in the regulations. Section 211.165 is therefore modified to allow greater latitude in establishing acceptance criteria, while retaining the basic requirements that acceptance criteria for sampling and testing, and for acceptance levels, be based on appropriate statistical quality control criteria. The Commissioner is convinced that sound statistical methodology should be applied to the procedures for testing of attributes or variables that impact on the quality of drug products and the evaluation of the results of such testing to determine acceptance or rejection of the lot. The uses of AQL and UQL are examples of statistically derived levels for acceptance or rejection. The Commissioner believes that more study must be given to this aspect of manufacturing practice and advises that in the future FDA will invite additional industry comment regarding revision of this section.

393. Several comments asked, with regard to § 211.165(e), whether official compendia test methods or methods from recognized sources have to be validated. The comments also recommended that guidelines be provided for documentation.

It is not the Commissioner's intent to require the validation of authoritative test methodology. Section 211.194(a)(2) of these regulations indicates that reference to official sources will suffice as documentation of a validated method. The intent of this section is that assurance of accuracy and reliability be provided for all test methods used. In the case of methods from official sources, such as compendia, reference to the source is documentation enough. For methods modified or developed by the firm or some other unofficial source, validation of the method must be provided. To clarify this issue, the final regulation in § 211.165(e) refers to § 211.194(a)(2).

394. A number of comments on § 211.165(f) proposed that laboratory reference standards received from official sources and/or with a protocol need not be tested. In addition, respondents recommended that secondary in-house standards should be tested against reference standards. Insertion of "standard solutions" was also suggested in this section. One respondent suggested inclusion of a requirement for an expiration date on standards.

In considering the comments in light of requirements elsewhere in the regulations, particularly § 211.160(b), the Commissioner concludes that the proposed requirements in § 211.165(f) should not be adopted as proposed. The Commissioner recognizes that laboratory reference standards can be interpreted to mean either standard reference materials prepared by a firm's own laboratories, or standards received from outside sources, e.g., official U.S.P. reference standards or FDA reference standards. Further, the Commissioner recognizes that complete testing by the user of many reference standards is not practicable although, generally, a specific identity test should be performed to verify such standard. The Commissioner finds that the requirements in § 211.160 provide the manufacturer the necessary flexibility to establish appropriate laboratory controls over the receipt or preparation of reference standards and to verify that such reference materials are suitable for their intended use. Therefore, proposed § 211.165(f) is deleted in the final regulation.

395. Several comments objected to the use of the word "statistical" in proposed § 211.165(g) (redesignated § 211.165(f) in the final regulations), stating that statistical criteria are not always relevant.

The Commissioner is deleting the word "statistical" in the final regulation because the phrase "and any other relevant quality control criteria" is sufficient to include statistical criteria where appropriate.

396. One comment requested deletion of the entire proposed paragraph (g) of § 211.165, because it is repetitive of § 211.84(e).

The Commissioner agrees that there is repetition between § 211.84(e) and proposed § 211.165(g) (now § 211.165(f)); however, he notes that the former does not cover drug products that are covered under the latter. The final regulation is revised to eliminate repetitious requirements.

397. Several comments objected to the wording of the second sentence of proposed § 211.165(g). They contended it is not possible to determine beforehand whether reprocessed material will meet appropriate standards and specifications.

The Commissioner accepts these suggestions and is rewording the provision, now § 211.165(f), so that it more clearly permits reprocessing of rejected materials.

398. Several comments argued that proposed § 211.165(g) should be worded to allow use of materials that deviate from standards and specifications that have no bearing on the quality of the drug product.

The Commissioner believes that it is clear in the context of this section that the standards and specifications referred to are those for acceptance or rejection. As stated elsewhere in this preamble, the standards for acceptance or rejection must be realistic while at the same time appropriate to assure the quality of the drug product. Any deviation from such standards is not acceptable. On the other hand, there is no requirement that a firm establish specifications or standards that do not relate to the quality of the drug product.

STABILITY TESTING

399. One comment on § 211.166(a) questioned the need to prepare a written testing program to assess stability characteristics of products such as borax and boric acid because methods of assay and analytical procedures for these materials are well documented.

The Commissioner notes that the written testing program includes more than just a description of the method by which a drug product is tested. It includes all the requirements listed in this section. If the test method used is an official compendial method or other authoritative method, then it would be sufficient to refer to the source of the method to satisfy that part of the requirement for written procedures for the testing program.

400. Several comments requested that the word "statistically" be removed as a modifer of "valid estimates of stability" in § 211.166(a)(1).

The Commissioner is modifying the final regulation to clarify that the statistical criteria apply solely to sample size and test intervals to provide assurance that every batch of drug product produced has essentially the same stability characteristics.

401. Several comments requested insertion of the words "where feasible" after the words "reliable, meaningful and specific test methods" in § 211.166(a)(3).

The Commissioner believes the phrase "where feasible" would suggest serious gaps in analytical methodology in drug manufacturing operations that in fact do not exist. The manufacturer has a responsibility to use test methods most suitable to assess the stability characteristics of his drug products.

402. Several comments requested the use of container closure systems for a stability testing program that are "similar" to the marketed container/closure system rather than the "same."

The Commissioner concludes that the container-closure system should be the same as the one used for marketing the drug product with regard to attributes that could possibly affect stability.

403. A comment on § 211.166 requested that the importance of stability testing of bulk active ingredients be emphasized because many manufacturers feel that stability testing applies only to finished dosage forms.

The requirement in these regulations for performing stability tests applies only to "drug products," which are defined in § 210.3(b)(4) as finished dosage forms. Therefore, it would not be appropriate to include a requirement for bulk drugs in these regulations. The Commissioner believes that appropriate stability testing for active ingredients is a requirement under section 501(a)(2)(B) of the act because all drugs, including bulk drug ingredients, must be produced in conformance with current good manufacturing practice. Stability testing of bulk drug ingredients is a current good manufacturing practice, and the Commissioner will propose to include it in the projected CGMP regulations for bulk drugs.

404. One comment requested the exemption of extremely stable compounds, such as calcium carbonate, from the stability testing requirements.

The Commissioner denies the request for the exemption. The stability of an active ingredient is not the only characteristic that should be examined in a stability testing program. A product may leach compounds from its packaging materials or be affected by heat or moisture in ways which could be detrimental to product quality without affecting its strength.

405. A comment asked whether the reference samples in § 211.166 can be taken from regular production batches for stability testing programs.

The Commissioner notes that § 211.166(b) clearly states that reference samples must be taken from regular production batches for stability testing programs.

SPECIAL TESTING REQUIREMENTS

406. Several comments on § 211.167(a) recommended that sterility and/or pyrogen testing for veterinary drugs be excluded as unnecessary.

The Commissioner finds that this paragraph does not establish whether any class of drugs is to be sterile and/or pyrogen free. The requirements of § 211.167(a) relate to drug products that purport to be sterile and/or pyrogen free.

407. One comment said an apparent conflict existed between § 211.167(a) and proposed § 211.165(d)(2), which would require destructive testing of the batch for the characteristics of sterility and/or pyrogenicity.

The Commissioner notes that proposed § 211.165(d)(2) specifically acknowledged that it would not be appropriate to destructively test the

entire batch. Section § 211.165(d) is reworded in the final regulation, with paragraph (d)(2) deleted, and the Commissioner sees no conflict between it and § 211.167(a).

408. One comment on proposed § 211.167(b) said collaborative laboratory studies have not established procedures for accurate and reliable testing for the presence of all types of foreign particles and harsh and abrasive substances. Alternative wording was suggested that would provide for such specifications and testing on an individual firm basis. Other comments recommended that the requirement be restricted to testing for metal particles, as is currently required by the compendia.

The Commissioner recognizes that tests for particles other than metal are generally not as precise as those tests for metal particles. The United States Pharmacopeia and FDA regulations for antibiotic ophthalmic ointments (21 CFR 436.206) contain requirements for testing for metal particles and limits for such particles. The majority of firms manufacturing ophthalmic ointments perform tests for other particle matter in addition to the U.S.P. or FDA required tests for metal particles. The Commissioner considers it a current industry practice for manufacturers to reduce or control the harshness and/or abrasiveness of ophthalmic ointment drug products that may be caused by any particles, including the components themselves. Components may, for example, contribute to harshness and/or abrasiveness of the ophthalmic ointment because of crystalline size and shape. The Commissioner is retaining provisions for appropriate testing other than those for metal particles. Some firms employ a subjective test for abrasiveness, such as rubbing a sample of the drug product between the fingers; the Commissioner does not consider this type of test adequate, however, unless the individual is qualified to conduct this organoleptic test.

409. One comment called attention to situations in which the coating of tablets in different coating pans during the manufacturing process may affect the release pattern and suggested that each pan he sampled, tested, and accepted or rejected on an individual basis.

The Commissioner recognizes the significance of proper coating in relation to its effect on the release pattern of active ingredients. Section 211.110 requires in-process controls to validate the performance of processes that may cause variability in the in-process material and the drug product. Sections 211.165 and 211.167 also require satisfactory conformance to finished drug product specifications. While he believes this to be adequate at this time, the Commissioner will consider the need for more specific requirements, either in the general CGMP regulations or in specific CGMP regulations for sustained release drug products or drug product tablets, because of unique problems that may be presented by tablet coatings, especially if active incredients are in such coatings.

RESERVE SAMPLES

410. Numerous comments on § 211.170(a) said reserve samples of components need not be kept for 2 years beyond the expiration date of the products containing them. There were numerous alternatives suggested, ranging from 2 years after use of the component to 1 year after the expiration date of the last drug product containing the component.

The Commissioner has concluded that the requirement for retention of samples for 2 years beyond the expiration date is not necessary. The 2-year requirement had been proposed to make the period consistent with the present alternative requirement of 2 years after distribution of the last drug product incorporating the component, if longer than a period of 1 year after the expiration date. The Commissioner is revising the final regulation in § 211.170 to require retention for 1 year after the expiration date of the last lot of drug product containing the component. Where no expiration date is required, such as for human OTC drug products meeting the criteria for exemption under § 211.137, the retention period is 3 years after distribution of the last drug product lot containing the active ingredient. The 3-year retention period also applies to the reserve sample of the drug product under § 211.170(b) and to retention of records and reports in § 211.180. Appropriate revisions are made in the final regulations.

411. Several comments recommended that hazardous and unstable materials be exempt from the reserve sample requirement in § 211.170(a). Other comments suggested that inactive ingredients also be exempted.

The Commissioner has concluded that storage of some types of materials may constitute an unnecessary burden or a safety problem. The section, as revised, will eliminate retention of inactive ingredients. He believes that deletion of retention requirements for inactive ingredients will eliminate most of the objections regarding hazardous and unstable materials; most of those materials cited by respondents are used as inactive ingredients. For those active ingredients that may be hazardous, though, the Commissioner concludes that the need for retaining samples of such active ingredients outweighs potential problems of storage.

412. A comment suggested that the word "appropriate" be inserted before the word "tests" in § 211.170(a) because some tests require extremely large quantities of component.

The Commissioner understands this comment to object to maintaining reserve samples when the amount of material needed to conduct the required tests is large. The Commissioner has concluded that the advantages of keeping such amounts of active ingredients outweigh any expected burden. He advises that this is an existing CGMP requirement.

413. One comment said it is not necessary to retain reserve samples of multiple shipments of the same lot number of components.

The Commissioner rejects this comment. Conditions of transit and storage can vary from shipment to shipment; such variable conditions can produce variations in the lots of different shipments.

414. Several comments on § 211.170(b) said the requirement for inspecting reserve samples of drug products annually is unnecessary in consideration of the requirement for stability studies and, further, that deterioration normally cannot be detected by inspection. Other comments said FDA should clarify its intent whether or not inspection was meant to require complete testing and whether such testing would be required if such would affect the integrity of the sample.

The Commissioner has concluded that the requirement for annual inspection is sound. Stability studies would not, in the usual sense, provide an opportunity for evaluating stability on a batch-by-batch basis. The intent of the regulation is not to require complete testing on each batch of reserve sample on an annual basis, but rather to require examination, such as would be done visually, and § 211.170(b) is revised to so state. The Commissioner recognizes that such examination would not provide the type of assurance that could be obtained by complete analysis, but the burden that complete testing would place on the industry would be unreasonable and unnecessary considering the requirements for establishing stability. The Commissioner is also revising § 211.170(b) to require annual inspection only if it can be done without affecting the integrity of the sample.

415. One comment said the amount of paperwork could be reduced if only samples that were found defective during annual inspection were recorded on the individual product record.

The Commissioner does not intend that there be a requirement for recording the results of examination re-

quired by this paragraph in the individual batch record for the product, if that is what the comment suggested. A record of samples must be kept so that test results can be correlated with each batch and the test results kept with other stability data.

416. Several comments said the requirement for retention of reserve samples in the same container-closure systems in which they are marketed is impractical in the case of very large or bulk containers.

The Commissioner has concluded that there are instances, for example those involving very large or bulk containers, where it would be impractical to store reserve samples in the same size container as is used for the marketed product. Although the Commissioner finds that the same immediate container-closure system is preferred for storage of the reserve sample, he is revising the final regulation to allow the use of an immediate container-closure system having essentially the same characteristics as the marketed container. This means, for example, that one size container may represent several sizes from the same batch, provided all containers were essentially the same except for size. The storage requirements for reserve samples differ slightly from the storage requirements for stability study samples in § 211.166 because to obtain accurate stability data it is essential to duplicate the conditions that could affect stability.

LABORATORY ANIMALS

417. A comment said this section (§ 211.173) should be deleted because the Laboratory Animal Welfare Act, enforced by the Department of Agriculture, already regulates the care and use of laboratory animals.

The Commissioner notes that the CGMP requirements for the maintenance and control of laboratory animals are intended to assure that animal test results are valid in that the results have not been affected by the use of animals that may have been exposed to adverse environmental conditions. The identification and maintenance of adequate records on animals are likewise intended to assure the validity of the test results. The intent of the Animal Welfare Act (7 U.S.C. 2131-2155) is, among other things, "to insure that certain animals intended for use in research facilities * * * are provided human care and treatment." Regulations implementing that act are quite detailed, but do not expressly deal with the two items of most immediate concern for drug quality purposes. The user of such animals for drug testing would, therefore, be required to comply with both the CGMP requirements of the act and the requirements of the Animal Welfare Act.

418. A comment said because not all manufacturers have animal facilities, the regulation should make it clear that § 211.173 applies only when animals are maintained for test purposes.

The Commissioner believes that it is clear that if animals are not used, the section does not apply. The intent of the section is not to require the use of animals, but rather to set standards applicable when animals are used. Therefore, the Commissioner sees no need to accept this comment.

419. One comment argued that the requirement for physical separation of animal maintenance facilities would be an undue hardship because it does not allow for flexible use of space by the manufacturer.

The Commissioner notes that § 211.173 does not speak of physical separation. The degree of separation in maintenance and control of animal facilities should be sufficient to assure that animal test results are valid in that the animal facilities do not contribute contamination to the drug product or the manufacturing facilities.

420. A comment said identification and recordkeeping for use of individual animals is unnecessary if the animal is used only once.

The Commissioner rejects this comment. Identification of each animal and adequate recordkeeping are a basic part of any biological test in order to assure accurate results. Even rodent species used only once should be accounted for on an individual basis to prevent inadvertent reuse, which may result in inaccurate test results. The Commissioner has dealt at some length with problems uncovered in reviewing drug testing in animals (see proposed regulations for good laboratory practice published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51206)).

PENICILLIN CONTAMINATION

421. A comment on § 211.176 said that because zero penicillin levels are required, raw material suppliers should certify that their products are penicillin free.

The Commissioner believes that, although drug manufacturers can at their own initiative request such certification from suppliers, FDA should not require suppliers of raw materials to test every lot of raw materials for penicillin, even when no reasonable possibility exists that they have been contaminated with penicillin. This would place an unnecessary burden on suppliers.

422. A comment said FDA is not qualified to test for penicillin contamination because FDA receives multiple samples in the same cartons, and they are kept together in the same room in the testing laboratory.

The Commissioner has concluded that there is no basis for this comment. Samples for cross-contamination testing are received by the FDA laboratory in sealed containers that are individually placed in sealed plastic or paper bags. Analyses for penicillin cross-contamination are conducted in a laboratory facility separate from that used for penicillin certification analyses. Positive and negative controls are run, and the analyses are conducted in laminar flow hoods under positive pressure. Thus, FDA is quite capable of determining the presence or absence of penicillin contamination.

XV. RECORDS AND REPORTS

GENERAL REQUIREMENTS

423. Some comments on § 211.180(a) objected to maintaining production, control, and distribution records for 2 years after the expiration date of the batch. They mentioned the increased cost of record storage and noted that adverse reactions, complaints, recalls, and other phenomena justifying record storage generally occur shortly after beginning distribution. Various time periods were recommended as alternatives. Several comments suggested a retention period of 2 years after the batch was approved for marketing.

The Commissioner finds that these records must be available for review for a reasonable time period beyond the expiration date of the products covered in the records to provide an opportunity for appropriate followup of any complaints or other adverse reports received during the entire marketing period. In reconsidering the extent of such retention period in light of the comments, however, the Commissioner has determined that a 1-year period following the expiration date will generally be adequate to assure that the records will be available for review if necessary. In the case of certain OTC drug products not being required to bear an expiration date because they meet the criteria for exemption under § 211.137, the record retention period is 3 years after distribution of the batch. This 3-year period is considered appropriate because the exemption is based on an assumption that such products will be used within 3 years after manufacture. Therefore, record retention for 3 years after distribution should be adequate to cover the time period during which records are most likely to be needed. The Commissioner recognizes that these final regulations will require retention of records beyond that currently required in the CGMP regulations. The CGMP regulations require the retention of certain records, e.g., batch production and control records, for time periods that are based on the distribu-

tion of the lot or, where applicable, the expiration date of the batch. The current regulations do not clearly specify the record retention period for other records. For some firms, the retention period for records will not change as a result of this regulation, as their practice is being incorporated in these regulations. In other cases, however, these regulations will require retention of records for a period of time longer than the minimum retention period specified in previous CGMP regulations. With specific regard to physical space for the storage of records, the Commissioner advises that the regulations do not generally require retention of original records, and that retention of suitable true copies in other forms such as microfilm is permitted. The Commissioner believes that, in keeping with modern business practices, there are many record retention systems that would fulfill the intent of the record retention provisions. Section 211.180(d) of the final regulations specifically provides for this flexibility.

424. One comment said § 211.180 should be deleted because section 703 of the act prescribes the maintenance of certain records that show the movement of articles in interstate commerce and does not mention the retention of records as described in § 211.180.

The Commissioner disagrees with this comment. Section 703 of the act permits FDA access to records of interstate shipment in the possession of carriers (i.e., transportation companies) or other persons receiving or holding food, drugs, devices, or cosmetics in interstate commerce. The provisions of section 703 do not apply to the manufacturers of drug products insofar as records of production are concerned.

425. One comment suggested that retention of records for components that have an indefinite stability or components that are used only occasionally to produce batches of drug products be excluded from § 211.180(b).

The Commissioner rejects this suggestion. The retention period is related to the expiration dates of the batches of drug products containing that batch of the component in order to assure that the records would be available for review during the marketing of the drug products and for a reasonable period thereafter. The Commissioner seriously questions whether any drug product can be considered indefinitely stable or would in fact carry an expiration date that would require record retention for an extraordinarily long time. Finally, the Commissioner notes that because the manufacturer has discretion to establish an expiration date that is less than the actual stability of the drug product, the manufacturer also has reasonable control over the periods during which he must retain records.

426. One comment said § 211.180(b) is overly inclusive and should be reworded to include only those components that come in actual contact with the drug product.

The Commissioner is unclear on the use of the word "component" in this comment. The definition of "component" appearing in the CGMP regulations would only include ingredients intended for use in the manufacture of a drug product, including those that may not appear in the final product. Section 211.180(b) limits records to components actually incorporated in the drug product. Thus, it seems obvious that the regulations only apply to components "that come into actual contact with the drug product" as requested in this comment. Therefore, the Commissioner cannot agree that the requirement as proposed is too extensive, and he sees no justification for revisions in the language in this paragraph.

427. Some comments suggested that reference to drug product containers and closures be deleted because these items are not subject to deterioration. One comment suggested that the requirement be retained for parenterals only.

The Commissioner does not agree that reference to container/closure record retention should be deleted because they are not subject to deterioration. The Commissioner is aware that some container/closure systems are subject to deterioration and there are other possible problems with containers and closures that may adversely affect the drug product. The purpose and intent of recordkeeping requirements is to be able to trace the complete history of a batch and thereby enable a firm and FDA to investigate fully any problems that may arise with either the product, the container/closure system, or both. Complete records would also make possible a determination of whether or not other batches or other drug products are or could be involved with the same problem. The failure to have these records available for any investigation could prevent the resolution of an undesirable condition. Therefore, the Commissioner is retaining this requirement to include all drug product containers and closures.

428. A comment on § 211.180(b) was submitted regarding the retention of records for compressed medical gases. The comment, which assumed that expiration dating would not be required for compressed medical gases, requested a retention period to be some logical and meaningful period.

The Commissioner finds that there is no justification for excluding retention of records required for compressed medical gases under this paragraph. The Commissioner has also decided to require expiration dating for medical gases.

428a. Several comments objected to reference to recordkeeping and record inspection requirements in proposed § 211.180 (c) and (d) insofar as they apply to over-the-counter (OTC) drugs and to "not new" drugs. These comments pointed out that section 704(a) of the act authorizes inspection of records regarding prescription drugs only and inspection of records regarding research data only on "new drugs" subject to section 505 of the act. One comment cited extensively from the legislative history of section 704 of the act indicating a congressional intent to limit the scope of inspection granted to FDA.

The Commissioner has reviewed the legislative history of the 1953 amendments (Pub. L. 83-217), which originally enacted section 704(a) of the act, as well as the amendments contained in the Drug Amendments of 1962 (Pub. L. 87-781 (1961)), which extended FDA's authority to review records for prescription drugs under the mandatory inspection authority of section 704 of the act. He finds that Congress did not include in the scope of the inspection authority under section 704 of the act (and its concomitant enforcement section under section 301(f) of the act) authority to inspect records regarding the manufacture of OTC drug products or research data on prescription drugs that are not "new drugs" as defined in section 201(p) of the act. The Commissioner also finds, however, that section 704 of the act does not exhaust the varieties of inspections that FDA may be authorized to make regarding such drug products.

Manufacture of any drug product without compliance with current good manufacturing practices renders the product adulterated, a prohibited act under section 301(b) of the act and a Federal crime under section 303 of the act. Thus, if FDA had reliable information indicating that an OTC or old drug product was being manufactured in violation of current good manufacturing practice, the agency could obtain a search warrant that would authorize FDA to inspect manufacturing records regarding the drug product to seek evidence regarding the alleged criminal offense.

A second type of FDA inspection into OTC drug production records would be in conjunction with inspections under Government-wide Drug Quality Assurance Programs. Manufacturers contracting to provide OTC drug products to the Department of Defense, the Veterans Administration, or the Public Health Service must, as a condition under those contracts,

permit FDA to inspect the plant, facilities, and records regarding the product to determine compliance with the Federal Food, Drug, and Cosmetic Act. If the manufacturer withdraws his consent for FDA to inspect, FDA will decline to accept the product on behalf of the purchasing Government agency, and if that agency so decides, the contract may be terminated.

A third example of an inspection authorized under the act is found in section 505(j)(2) of the act where a manufacturer must permit inspection of records regarding new drugs which are required under section 505(j)(1) of the act; failure to do this is a prohibited act under section 301(e) of the act. It is conceivable that an NDA for an OTC drug would be subject to record-keeping requirements regarding manufacturing activities, and if so, FDA could inspect these records, notwithstanding section 704 of the act.

This does not necessarily identify all circumstances in which FDA may be authorized to make an inspection of records regarding the manufacture of an OTC drug product or research data on "not new" drugs. See, generally, Horton, "Warrantless Inspection Under the Food, Drug, and Cosmetic Act," 42 G.W. Law Rev. 1089 (1974).

The purpose of § 211.180(c) is to assure that all appropriate records were properly collected, indexed, and held at the site where an inspection would occur so that, in the event of an authorized inspection by FDA, these records would be readily reviewable by the FDA inspector. Otherwise, an unnecessary delay may occur if the manufacturer had to locate and collect the appropriate records for an inspection. It is not the intent of these paragraphs of the regulations to compel a manufacturer to submit to an inspection that was not legally authorized. To clarify this, the Commissioner is inserting the word "authorized" before the word "inspection" in § 211.180(c).

429. Several comments objected to the requirement that records be readily available at the establishment where such recorded activities take place on the grounds that most firms with multiple facilities maintain central record storage facilities and that compliance with § 211.180(c) would require needless and unnecessary duplication of the records and storage facilities. These comments suggested that provision be made for central record storage sites, provided that the requested records be made available in a reasonable period of time.

The Commissioner does not agree with the contention that keeping these records or copies of them at the establishment where the activities took place would be unnecessary and would require needless and unnecessary duplication of the records and facilities. He is of the opinion that most firms today keep the records or copies of them at the site where they were generated. These critical records must be available to both plant personnel and FDA for review. To require that plant personnel and FDA investigators place orders for specific records to another facility and then wait for delivery would not be prudent. There is the distinct probability that operating under these circumstances would greatly extend the time needed to conduct an investigation of a problem or to conduct the required inspections.

The Commissioner does believe, however, that records that can be immediately retrieved from another location by computer or other electronic means meet the requirement of being readily available at the establishment. The final regulation includes this provision. As the Commissioner stated in reply to other comments regarding record storage, these regulations do not preclude the use of other record storage systems, such as microfilm or microfiche. Where other systems are employed there must be associated capability for viewing and copying. The final regulations include a new § 211.180(d) to clarify these provisions.

430. One comment suggested that the regulation provide guarantees that the FDA investigator will not copy these records or if they are copied, that they will not be released under the Freedom of Information Act.

The Commissioner cannot agree with the first suggestion. There are many instances where the investigator who makes the inspection does not have the time to review records at the establishment for all of the facets involved. In addition, this suggested provision would result in an inordinate expenditure of FDA resources to provide adequate time for a complete review of the records at the plant site. The Commissioner believes that true reproduction of records, compared with handwritten copies, assures their authenticity and decreases inspectional time. While the copying of appropriate records has always been implicit in CGMP regulations, there have been instances where investigators were restricted by manufacturers to handwritten copying of the records. Therefore, § 211.180(c) is being amended in the final regulation to clarify that records are subject to copying during the course of an inspection.

The Commissioner also rejects the respondent's suggestion that documents not be released under the Freedom of Information Act. The Commissioner is required by law to release documents in his possession unless they contain information or are of such a nature that a request for release could be denied. In this regard, the Commissioner specifically refers to the FDA regulations describing public disclosure of "trade secret" information in FDA files (21 CFR Part 20, particularly § 20.61).

431. Numerous comments objected to § 211.180(e) (proposed as § 211.180(d)) on the grounds that the requirement for the generation of a written summary is not current practice and would have an unnecessary inflationary impact without any noticeable effect on improving the quality of drug products in general. Some of these comments argued that the proposal did not specify what data were to be summarized. Other respondents questioned the authority of the FDA to require these summaries. Numerous additional comments were submitted suggesting that these summaries be prepared "when necessary" or "when needed." Several other comments objected to the required retention period.

The Commissioner has carefully considered the extensive comments regarding the proposed requirements for written summaries and concludes that revisions in this paragraph are justified. The purpose is to provide reliable procedures for a manufacturer to review the quality standards for each drug product. The Commissioner agrees that mechanisms other than written summaries may be appropriate for such evaluation. Therefore, the final regulation is amended to require that manufacturers establish their own written procedures for annual evaluation of the quality standards for each drug product. While not specifying what review mechanism must be used, the Commissioner encourages the use of written summaries as one practical means of drug product review. The Commissioner believes that some manufacturers are currently using such written summaries to good advantage in establishing drug product profiles.

432. Several comments objected to § 211.180(f) (proposed as § 211.180(e)) on the basis that it is an unwarranted intrusion into corporate duties and responsibilities, and adherence to this requirement would not affect the integrity of the drug product. Some of these comments suggested an exclusion for small businesses because the corporate officials would be writing themselves reports. Still others suggested limiting these reports to significant findings.

The Commissioner believes there are sound reasons for this proposed requirement. From time to time it has been the agency's experience that corporate officials have not been advised of potential or real adverse conditions brought to light either by the firm's own quality control system or by FDA. As a result, corrective actions have not

been instituted where they might have been, had company officials been aware of such conditions. Correspondence from FDA to firms regarding inspectional findings and recalls is directed to top officials as a matter of policy, but not all conditions specified in § 211.180(f) are the subject of inspections or recalls, and even in the case of inspection and recalls there may be a period of time before FDA correspondence which deals with the subject is issued. The Commissioner does not believe that the requirements of § 211.180(f) are burdensome and is confident that the concept of keeping officials informed of such situations as specified in § 211.180(f) is, for the most part, current industry practice.

The Commissioner rejects the argument that the requirements of this paragraph are an unwarranted intrusion into corporate duties. They will provide added assurance that efforts are being directed toward the prevention and/or correction of conditions that could affect the quality of the drug product. Moreover, responsible officials already have very rigid legal duties to be aware of, and to take action upon, conditions contributing to drug adulteration (*United States* v. *Park*, 421 U.S. 658, 1975; *United States* v. *Dotterweich*, 320 U.S. 277, 1943).

In view of the comments, however, the Commissioner is deleting the proposed requirement regarding routine quarterly written reports in order to allow manufacturers flexibility in establishing procedures to keep appropriate management fully informed as to important matters involving possible quality control problems. In addition, the final regulation provides an exception for officials, whether in large or small firms, who are personally involved or immediately aware of investigations, recalls, reports of inspectional operations, and regulatory actions relating to CGMP regulations.

EQUIPMENT CLEANING AND USE LOG

433. Several comments on §§ 211.182 and 211.186 recommended that the requirement for signatures be deleted or modified to provide for initials, or other specific employee identification, e.g. an employee number.

The Commissioner is persuaded that the requirement for a full signature may not be warranted in view of the space that would be required in the records and the burden of continually writing a full signature on records that are repetitive. For less repetitive type of records, such as master records referred to in § 211.186, the Commissioner has decided to retain the requirement for a full signature. The Commissioner rejects the suggestion that a distinctive employee number be allowed because it would detract from the concept of personal involvement. Numbers, in the Commissioner's opinion, may be easily recorded by persons other than those who actually perform the function.

434. Some comments suggested that the word "strength" be deleted from § 211.182 as superfluous because this information is readily derived through the lot or batch number.

The Commissioner agrees that the word "strength" can be deleted. The remaining required information is sufficient to identify the batch.

435. Several comments objected to the requirement in § 211.182 that an individual written record of all equipment cleaning and maintenance would have to be double-checked and signed. This requirement could include logs for stirrers, scoops, and ladles.

The Commissioner agrees that this requirement, as proposed, could be construed to include such items as ladles, stirrers, scoops, spoons, and spatulas. Therefore, the word "major" is being inserted before "equipment." This change does not affect the responsibility of assuring that all utensils and other equipment are properly and adequately cleaned before re-use, but only documentation of such activities.

436. One comment on § 211.182 doubted the need for routinely double-checking cleaning and maintenance. it argued that this would require the checkup person to be present during the operation. A second comment said the requirement for checking routine maintenance would be overly burdensome.

The Commissioner notes that the purpose of this requirement is that a second person determine that appropriate cleaning and maintenance was performed. He does not believe that this necessitates that the person doing the checking be present during the entire operation. Changes in the final regulation clarify this intent and also exclude from the required checking routine maintenance activities such as lubrication and adjustments.

437. Several comments on § 211.182 objected to keeping logs inasmuch as the information is readily available in other records, such as the batch record.

The Commissioner rejects this view because in most instances batches are not processed consecutively on any one piece of equipment. If the practice were not followed and one attempted to determine the chronological use of a particular piece of major equipment to ascertain, e.g., whether several batches were affected by a malfunction, a burdensome review of numerous batch records would be necessary.

438. Some comments said logs required in § 211.182 are not necessary when equipment is dedicated to a single product.

The Commissioner agrees that if equipment is dedicated to the manufacture of one product, the requirement for individual equipment logs would not be necessary, provided that lots or batches of such products follow in numerical order and are manufactured in numerical sequence. In such cases where the use of dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The Commissioner is revising this section accordingly.

439. One comment said § 211.182 is an unnecessary burden on the manufacturer who places reliance on the drug product's final testing.

The Commissioner is aware that dirty or poorly maintained equipment can introduce characteristics to a drug product that may not be detected by final examinations. Moreover, it is in the manufacturer's interest as well as the public's to prevent quality assurance problems, rather than simply detect them. Therefore, the Commissioner rejects this comment.

440. Comments objected to the requirement for one log for each piece of equipment containing the information regarding cleaning and maintenance when a portion of the cleaning or maintenance may be performed either at another location or by a different department.

The Commissioner notes that it is not the intent of this section to limit the number of logs for each piece of equipment to one. The intent is that there be one or more logs for each major piece of equipment which, in their entirety, contain the information required by this section. The Commissioner does not believe the section implies otherwise.

COMPONENT, DRUG PRODUCT CONTAINER, CLOSURE, AND LABELING RECORDS

441. Several comments requested an exemption of veterinary drug products from the requirements in § 211.184 (a) and (c). For drug product containers and closures, it was also suggested that the section be modified to indicate that the requirements regarding product containers and closures should apply only to the drug products intended for human use.

The Commissioner rejects these comments. He sees no sound arguments that drugs intended for veterinary use should be subjected to lesser controls than human drug products.

442. Several comments objected to the proposed requirements in § 211.184(a) for the lot history of drug product containers and closures. Comments were that existing controls product containers and closures are sufficient and in some instances the supplier's lot number and the location of the manufacturer are not known.

Another comment expressed concern that reporting of the name and location of the prime manufacturer "if known" was not sufficient and such reporting should be mandatory.

The Commissioner cannot agree that the information relating to the lot history of drug product containers and closures is not important in providing prompt and accurate identification of such lots, when necessary. Generally, the required information is already available and recorded by most manufacturers, but may not have been previously organized in such a manner as to facilitate identification of drug product containers and closures. The Commissioner acknowledeges that, occasionally, information such as the supplier's lot number or location of the manufacturer is not known. The proposed regulation already provided for the instances where the name and location of the prime manufacturer, when different from those of the supplier, is not known, and the final regulation also takes into account that a supplier's lot number may not always be available. This modification, however, does not diminish the control over such drug product containers and closures by the drug manufacturer. The receiving code, specified in § 211.80, will serve to identify the received lot to the drug manufacturer. The Commissioner encourages all suppliers to adopt batch or lot identification to aid in locating components, drug product containers, and closures in the event it becomes necessary to do so to protect the public health.

About the comment for mandatory recording of the prime manufacturer in all cases, the Commissioner concludes that such a requirement is not necessary. Because such information is usually readily available, however, and may be useful to the manufacturer in considering the suitability of suppliers or allow for tracing the complete history of the component, container, or closure, it should be recorded when available.

443. One comment on § 211.184(b) recommended substituting the phrase "subsequent disposition assigned to the material" for the phrase "conclusions derived therefrom" in the last line of this paragraph because under the sections cited in the proposed paragraph, the only possible decisions are release, restrict, reprocess, or reject.

The Commissioner cannot agree with this comment and believes the comment may have misinterpreted the proposed requirement. Results of tests or examinations required under the sections cited in this paragraph are clearly to be included, but all tests and examinations must be considered. There are a wide range of conclusions that may be drawn from results of tests or examinations. For example, a test failure resulting from improper testing procedure would be recorded, but the lot would not necessarily be rejected based on that one improperly performed test. The Commissioner finds that this paragraph should be finalized as proposed.

444. Many comments addressed § 211.184(c). Most agreed that an inventory record and reconciliation for drug product components was appropriate, but objected to inventory records and reconciliation for drug product containers and closures. Others contended that inventory records, but not reconciliation, were also appropriate for drug product containers and closures. Arguments were primarily that recordkeeping to this extent was unnecessary, burdensome, and not current practice. Some comments were concerned that extensive records and reconciliation would be required for packaging materials such as cotton filler material used in packaging tablets and capsules. Several comments recommended changes in the proposed language that would clearly require that the inventory record be sufficient to establish the batch or lot of drug product in which component, drug product container, and closure are used.

The Commissioner has reconsidered the need for individual inventory records and reconciliation of the use for components, drug product containers, and closures. He finds that individual inventory records are necessary to provide an adequate history regarding the use of components, drug product containers, and closures. To clarify the intent that such inventory records are intended to allow for determination as to the batch or lot of drug product associated with the recorded inventory, the Commissioner is modifying the proposed wording in this section (§ 211.184(c) and in § 211.188(g)).

The Commissioner agrees with the comments that reconciliation of the use of each lot of drug product container and closure should not be required. Although there are instances where such reconciliation could be valuable to the drug manufacturer, it should not be mandatory for all drug products and all drug manufacturers. The CGMP regulations elsewhere provide considerable control over the approval and use of drug product containers and closures. Because of the more critical nature of the ingredients, on the other hand, each drug product component must be inventoried and its use reconciled in order to provide added assurance of product integrity.

The Commissioner emphasizes that this section does not pertain to all packaging materials, but only drug product containers and closures. Thus, individual inventory records for packaging materials such as cotton filler and package liners are not required under this section, although records regarding the receipt, examination or testing, and disposition for packaging materials generally are required in § 211.122, particularly in paragraph (c).

445. One comment objected to § 211.184(d) on the grounds that it could be interpreted to require each person on the manufacturing line who makes an inspection to record that inspection as it is made. The comment recommended deleting the word "all" from the paragraph.

The Commissioner finds that this paragraph is intended to provide for the documentation of the examination of labeling as required elsewhere in the CGMP regulations. To eliminate the possibility of misinterpretation, § 211.184(d) is revised by substituting the words "the examination" for the words "all inspection" to conform more closely to the language used elsewhere.

In considering the final regulation, the Commissioner finds that a new § 211.184(e) is desirable to clarify that records regarding the disposition of rejected drug product containers, closures, and labeling must be maintained.

MASTER PRODUCTION AND CONTROL RECORDS

446. One comment noted that the phrase "master production and control records" as used in § 211.186(a) was not limited to "appropriate master production or control records" as in § 211.188(a), and requested clarification in regard to use of the word "appropriate."

The word "appropriate" in § 211.188(a) is intended to denote the master production or control record that is appropriate for the particular batch for the drug product. The Commissioner believes both paragraphs as written are clear in this regard.

447. Several comments argued that the "full signature, hand written" is not necessary and that the paragraph should be changed to allow for other means of identifying the persons who prepare and check the master production or control cards, such as initials, registered initials and/or signature stamps.

The Commissioner believes the requirement for a full signature is appropriate when applied to master records. In the past, FDA has on occasion found instances where firms could not identify the person or persons whom the initials were intended to represent. Further, the Commissioner does not believe this requirement to be burdensome because master production and control records in most cases would be infrequently established or changed.

448. One comment proposed acceptance of other validating techniques in the first sentence of § 211.186(a) on the grounds that verification can be accomplished by machine.

The Commissioner is not aware of how master production and control records can be totally prepared and verified by machine. Although calculators or computers might assist in preparation and verification by aiding the persons involved, the initial information would have to be fed into the calculator or computer by a responsible person, and a second responsible person would have to verify that the hard data fed into the machine were valid. Where appropriate, the use of automated equipment and computers is allowed under § 211.68 provided hard data are kept of certain records such as master production and control records.

449. One comment said the words "where appropriate" should be inserted after "strength" in the first line of § 211.186(b)(1).

The Commissioner rejects this comment because it is appropriate to include the strength of the drug product on the master production and control records.

450. One comment said § 211.186(b)(4) should be revised to require use of the metric system of measurement only.

The Commissioner rejects this comment. While the metric system is used to a great extent in the drug manufacturing industry, a requirement for conversion to the metric system as the sole method of measure could be an unnecessary burden upon industry at this time. Such a requirement may be imposed in the future by the Commissioner, in keeping with national laws on conversion to the metric system and good manufacturing practice.

451. One comment said the requirement in § 211.186(b)(4) for using the same weight or measure system should be deleted or revised to allow firms to change the master formulas gradually over a period of years or as the drug product is reformulated.

The Commissioner believes that the large majority of drug firms already comply with this requirement. The Commissioner notes that the effective date of this final regulation allows sufficient time for the remaining firms to comply with this section and therefore rejects the suggestion that firms be allowed to change their systems over a period of years.

452. One respondent recommended that the requirement for "using the same weight system" in § 211.186(b)(4) should not be applied to veterinary drugs because these are often produced in large volumes or masses.

The Commissioner finds no justification for exempting veterinary drugs from this requirement. The fact that large volumes or masses are involved is not a convincing argument that the requirements for use of a consistent measurement system should not apply to the manufacture of veterinary pharmaceuticals. Drug products for human use are also often manufactured in large volumes or masses.

453. One comment on § 211.186(b)(7) said repetitious calculation of percentage of theoretical yield adds nothing to the integrity of the product.

The Commissioner rejects this comment. The regulation does not require "repetitious" calculation of theoretical yield; instead, one calculation must be made part of the master production and control records, together with appropriate tolerances from this calculation beyond which an investigation for manufacturing errors would be required.

454. One comment said the theoretical yield percentage, which if exceeded would require an investigation under § 211.192, should not be included in the record as required in § 211.186(b)(7) because the investigation is the responsibility of the quality control unit.

The Commissioner does not understand the reasoning behind this comment. The fact that this information appears in master or batch records does not displace responsibility of the quality control unit.

455. One comment said the requirement in § 211.186(b)(7) for a statement of theoretical yield does not take into account that there is sometimes a shortage in the actual yield because a manufacturer may discard a portion of a batch due to a problem with the "pharmaceutical elegance" of the product.

The Commissioner sees no reason to accept this comment. The purpose of the theoretical yield requirement is to serve as an indicator of a possible error when compared to the actual yield. If the manufacturer can account for the shortage in the actual yield of the product by documenting that a definite portion of the lot was discarded because of its inelegance, the regulations have been followed.

456. One comment argued that the label should be required to be maintained on file and not physically attached to the master production or control record.

The requirement does not state that the label has to be glued or stapled to the master record, for example, if this is what the respondent means by "physically attached." Since 1963, the CGMP regulations have required that a specimen or copy of each label be included in the master production and control record. This requirement is needed in order to make the master production and control record complete with respect to all aspects of processing, and should not be changed.

457. Several comments regarding §§ 211.186(b)(8) and 211.188(b)(8) said lithographed bottles, cans, and ampules cannot be kept on file.

The Commissioner notes that the final regulations provide that a "specimen or copy" be included in the master and batch production or control record. A photograph, photocopy, or other accurate reproduction will fulfill the intent of these sections.

BATCH PRODUCTION AND CONTROL RECORDS

458. One comment on § 211.188 said batch production and control records should be permitted to be extensively simplified because lots are repetitive and are usually processed on identical equipment in an identical manner for months or years.

The Commissioner notes that this comment fails to specify what simplifications are proposed. The purpose of these regulations is to provide for a written system which, when followed, results in a reproducible high-quality drug product. The Commissioner believes that "simplifying" the batch and record controls by reducing the types of information required would have an adverse effect upon the quality of the drug product and would not reflect current industry practice. On the other hand, use of forms to ease the recording of information (without omitting any) would fulfill the provisions of this section.

459. A comment said there is no need to check a batch production and control record, as required in § 211.188, if it is a photocopy reproduction of the master production and control record. Further comment recommended that the words "where necessary" be inserted after the word "accuracy" in the third line of § 211.188(a).

The purpose of this requirement is first of all to make sure that the correct master production or control record has been copied. Also while photocopying may be the most accurate and preferred means of producing a batch production and control record, no system is infallible. For example, a spot or mark on the plate glass surface of the copier could result in the obliteration of a letter or the addition of a period onto the photocopy reproduction, and this might change the formula. The Commissioner believes that the checking, dating, and signing of a batch production and control record is always necessary to assure that such records are correct.

460. A comment said § 211.188 should explicitly allow the use of batch production or control records produced by a computer.

The Commissioner notes that § 211.68 clearly permits the use of com-

puters in the manufacture, processing, packing or storage of drug products. Section 211.188 does not limit the means by which a batch production or control record may be produced. The Commissioner does not believe that repetitiously providing for the use of computers or any other means of reproducing batch production and control records in each section where it is applicable is necessary.

461. Several comments said § 211.188 is unclear as to what records are encompassed in the requirements. Specifically, one asked whether the term "appropriate" in § 211.188(a) allows a manufacturer to use a "manufacturing ticket" that does not contain all the information in the master production or control record.

Although the Commissioner is not sure of the intended meaning of "manufacturing ticket," he notes that the word "appropriate" in § 211.188(a) refers to the master production and control record for the size of batch, strength, and dosage form that is to be manufactured. The term "appropriate" is not intended to allow a manufacturer to delete any pertinent information from the batch production and control record. As stated in this paragraph, the batch production and control record shall be "An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed." If a portion of the batch production record were sent to a particular department that is involved only in the operation covered by that portion of the batch record, the Commissioner would consider that practice to be consistent with the requirements of this section.

462. A comment said provisions should be made in § 211.188 for batch production and control records only to the extent that each operation is performed by each establishment, because some operations such as packaging are often performed by another firm.

The Commissioner advises that a new § 210.2(b) is added to these final regulations to clarify the applicability of CGMP regulations to persons engaged in only some of the operations subject to these regulations.

463. Several comments said the words "and after" should be deleted from § 211.188(b)(6) as requiring unnecessary and burdensome duplicative inspections.

The Commissioner rejects this comment. To prevent mixups and to reconcile the label count after packaging, it is necessary to inspect the premises after each packaging operation. It is also necessary to inspect before the next packaging operation because foreign materials other than those from a previous packaging operation could be introduced into packaging operations. For those packaging operations that are "back-to-back" with essentially no time interval, a single inspection will meet the requirement of § 211.188(b)(6).

464. Comment on § 211.188(b)(7) said the statement of percentage of theoretical yield should be ascertained only at the completion of compounding and packaging because some drug manufacturing processes are not complicated operations.

The Commissioner concludes that this section will have to be applied in consideration of the complexity of the processing needed for each drug product. The calculation of the percentage of theoretical yield only after completion of compounding and packaging may be appropriate in some cases where, for example, drug product manufacturing is not complicated. The revised final regulation should clarify that this flexibility is intended.

465. A comment said radio- pharmaceuticals should be exempt from the requirement in § 211.188(b)(7) for developing theoretical yield data because its determination would involve reassay of the unused bulk radioactive material.

The Commissioner believes that this section as revised in the final regulation responds to this comment in that the requirement applies at "appropriate stages" of processing. The Commissioner also notes that this section does not specify the tolerance levels for acceptance of actual yields. Such levels will vary depending on the drug product being produced.

466. Several comments said the words "or if impractical, a label revision number," should be inserted after "specimen" in § 211.188(b)(8).

The Commissioner rejects this comment. This requirement provides a ready means for production personnel to verify visually the processing record against what is actually being processed and provides a more complete record than a label revision number might furnish.

PRODUCTION RECORD REVIEW

467. One comment on § 211.192 indicated that accountability is of more concern than actual versus theoretical yields.

The concept of accountability is implicit in the use of theoretical yields and particularly in the comparison made between actual and theoretical yields. The material produced, considering accountable losses, is the actual yield. Comparison of the actual yield with the theoretical yield, i.e., what should have been produced, requires a determination of acceptability. The actual yield is acceptable if losses have been satisfactorily accounted for.

467a. One comment proposed replacing the word "all" at the beginning of § 211.192 with "batch."

The Commissioner agrees that the intent of this section is to require review of those records that directly relate to batch production and control. Therefore, the comment is adopted in the final regulation.

468. A comment described the quality control unit review of production and control records in § 211.192 as an excessive requirement because it would include reviews of internal manpower or labor use records.

The Commissioner does not intend that documents outside those which impact on drug product identity, strength, quality, and purity should be reviewed by the quality control unit for release purposes. The regulation is revised to clarify this.

469. One comment proposed that a single individual should certify that the review for quality control considerations required in § 211.192 has been made.

The Commissioner finds that because of the wide variety of activities and operations which the quality control unit is responsible for approving or rejecting, a number of different methods of expressing or indicating approval or rejection may be appropriate. For example, in some firms the "Director of Quality Control" may personally sign all approvals or rejections. In other firms, however, the "Director of Quality Control" may delegate this responsibility to subordinates. However, the Commissioner does not believe it is appropriate for him to dictate that specific persons be solely authorized to perform these functions.

LABORATORY RECORDS

470. One comment suggested revising § 211.194(a) by inserting the word "required" before "test," because not all laboratory tests are germane in determining the product's acceptability. It was stated that some tests are primarily for informational purposes and should not be part of the records.

The intent of this section is that laboratory records include data derived from tests that are necessary to assure compliance with established specifications and standards. The final regulation is revised accordingly.

471. Several comments suggested that the word "quantity" be deleted from § 211.194(a)(1) because this information is contained in other records, and the requirement is excessive and of no value.

The Commissioner rejects these suggestions because it would be pertinent, upon review, to determine whether the size of sample drawn is representative. A record of the size of the sample drawn also allows for a reconciliation

of the amounts used for each test with the amount of total sample. This could provide important information for any investigation that may be instituted following marketing of the batch or lot. The Commissioner does not believe that recording the size of the sample is burdensome.

472. A comment questioned the need for recording in the laboratory records the date of receipt of a sample by the laboratory, as required by § 211.194(a)(1). The comment suggested use of the date of sampling instead.

The Commissioner does not agree that recording the date of receipt of a sample by the laboratory is unnecessary. Laboratories commonly log samples showing the date that they are received by the laboratory. Some analyses, such as moisture content of a granulation, may be influenced by the elapsed time between sampling and assay. It therefore becomes necessary to know both when the sample was drawn and when it was received by the laboratory. The final regulations are revised to clarify that both the date of sampling and the date of receipt for analysis and testing are required.

473. One comment on § 211.194(a)(1) questioned the neccessity of describing the sample if the other specified information is available.

The intent of this requirement is to provide enough of a description to identify the sample properly, such as the name of the drug product and the form of the sample, e.g., granulation, raw material, or powder. The Commissioner concludes that this is reasonable information to require and, that the requirement reflects current practice.

474. One comment said the meaning of the words "source" and "quantity" in § 211.194(a)(1) is not clear. The comment further stated that "quantity" could mean the number of sample containers, which is a reasonable requirement, or it could mean the weight or measure in each sample container, which is not reasonable.

The Commissioner rejects the argument that the word "quantity" in the context of § 211.194(a)(1) could be interpreted to mean only the number of sample containers with no reference to the amount of sample in each container. The size of sample containers could range, for example, from a liter container to a container that holds only a few grams. Further, the Commissioner does not believe this requirement to be either unreasonable or burdensome.

The Commissioner also concludes that the meaning of the word "source" in § 211.194(a)(1) needs clarification. "Source" of the sample is intended to mean the location, e.g., a specific drum number and storage area or in-process phase. The final regulation is revised in this regard.

475. Several comments suggested that the last sentence of § 211.194(a)(2) be deleted because the requirement was stated in the second sentence in this paragraph.

The Commissioner does not agree with these comments. The last sentence of § 211.194(a)(2) requires that testing methods, whether such methods have been developed by the manufacturer or are from official compendia, be verified under actual conditions of use. The Commissioner does not believe that the requirement in this last sentence is explicitly stated previously.

476. One comment argued that the requirement in § 211.194(a)(2) that laboratory records contain a statement of each analytical method used in the analysis of a sample should be limited to assays and should not extend to other tests such as physical tests.

The Commissioner does not agree that the requirement should be limited to assays of components of drug products. Tests or examinations other than assays are an integral part of the history of a drug product, especially in situations where a physical test might be as critical as an assay—for example, in determining particle size, dissolution rate, or tablet hardness. Recognizing, however, that this section as worded in the proposal is somewhat ambiguous in this regard, the Commissioner is rewording the final regulation to reflect that the requirement applies to all tests, including examinations and assays.

477. Several comments suggested that the words "where appropriate," "where meaningful," or "where required" be added at the end of § 211.194(a)(3). One comment reasoned that the size of the sample is not pertinent for many laboratory tests, e.g., melting point, infrared identification, qualitative colorimetric spot tests, and pH.

The Commissioner accepts the intent of these suggestions and is revising § 211.194(a)(3) accordingly by adding the phrase "where appropriate" in order to provide for test procedures where a nonspecific weight or measure is used.

478. Several comments requested deletion of the requirement in § 211.194(a)(4) to include all "graphs, charts, and spectra from laboratory instrumentation" in laboratory records because they are not needed and would create additional files.

The Commissioner believes that all graphs, charts, and spectra used to show a product's acceptability must be retained for future reference. These records would be needed to carry out any investigation required under these regulations.

479. Several comments requested deletion of the requirement in § 211.194(a)(4) that laboratory records include data on testing of drug product containers and closures.

The Commissioner believes that the records generated showing the acceptability or nonacceptability of the containers and closures are as necessary as those for components, in-process materials, or drug products and therefore rejects the request for deletion.

480. Several comments requested § 211.194(a) (4) and (5) be revised to take into account calculations and data derived from automatic testing equipment, such as computers.

The Commissioner notes that § 211.68 already provides for calculations and data derived from automated equipment and that such provisions need not be restated in every section where they would apply.

481. In considering comments relating to proposed § 211.194(a)(6), the Commissioner concludes that those requirements are more appropriately codified as § 211.194(b). Specific comments are responded to beginning with paragraph 488 below.

482. Some comments on proposed § 211.194(a)(7) (now § 211.194(a)(6)) recommended that the phrase "drug product container, closure" be altered to apply only to human drug product containers and closures.

The Commissioner finds that recordkeeping should apply to pertinent information regardless of the intended use of the drug product.

483. Several comments on proposed § 211.194(a)(7) objected to requiring the laboratory to make a comparison of the test result against an established standard, especially where a standard is not known to the laboratory personnel. Some of these comments suggested alternative wording to clarify this. One comment objected to requiring this statement if the reported result was close to the specification.

The Commissioner believes there must be established standards that all test results are compared against, whether they be precise standards, an acceptable range of values within maximum and minimum values, or the absence or presence of certain attributes. The Commissioner does not understand how respondents would evaluate the significance of test results if no standards for comparison exist. Therefor, this requirement as proposed is retained in the final regulation.

484. Several comments on proposed § 211.194(a)(8) (now § 211.194(a)(7)) suggested the use of alternative systems of identification instead of a full signature of the person who performs each assay or test. Suggested alternatives were employee numbers or initials.

The Commissioner agrees that a full signature is not needed in this instance and therefore is amending § 211.194(a)(7) to allow the use of initials.

485. Several comments suggested that § 211.194(a)(8) (proposed as § 211.194(a)(9)) be deleted on a variety of grounds—it would be a waste of technical manpower; it would be inflationary; and it is not current practice for the veterinary industry. Other comments suggested provision for a random review or the insertion of the phrase "when such records are audited."

The Commissioner has evaluated all these comments in light of the objective of having independent verification of the laboratory work to insure that the proper procedures were used and followed, that the calculations are correct, and that the record is complete. A review of laboratory records is necessary to insure that the correct test was performed, that the calculations are correct, and that the record is complete. This is not wasteful of resources or unjustifiably costly.

The Commissioner finds it difficult to accept the stated premise that the veterinary drug industry does not review laboratory records to determine whether the proper tests, assays, or examinations have been performed and that the results are valid. It is the Commissioner's belief that drugs for veterinary use, like drugs for human use, must be produced under appropriate control.

The Commissioner rejects the suggested revisions that limit the review to a random basis or to periodic audits. The analytical record for each batch must be reviewed in order to detect whether or not the correct procedure was used, the calculations are correct, and the laboratory record is complete.

486. Some comments suggested that the records reviewed need not always be "original."

The Commissioner notes that "original" is used to convey the intent that the records reviewed be those which contain the data used in conducting tests. The original records give the necessary assurance that complete information is being reviewed. Further, the Commissioner believes it is feasible, and does not believe it is burdensome, to require that the original records be reviewed.

487. One comment suggested that the word "signature" be substituted for the word "endorsement" in § 211.194(a)(8).

To clarify § 211.194(a)(8), it is revised to state that the records shall consist of initials or signature.

488. One comment on proposed § 211.194(a)(6) (now § 211.194(b)) suggested inclusion of the phrase "or suitable reference to" after the phrase "a full description of."

The Commissioner agrees that it is not necessary to describe fully a modification of an established method each time the method is used. The Commissioner has appropriately reworded this requirement in the final regulation to clarify this issue.

489. One comment on proposed § 211.194(a)(6) suggested that the word "sample" be substituted for the word "material" because "material" is undefined.

The Commissioner believes that the meaning of "material" is clear when considered in the context of this section, now codified as § 211.194(b). The term is used broadly to denote any materials, for example components, in-process materials, drug products, containers, or closures, which are tested in consideration of the quality of the drug product.

490. One comment on proposed § 211.194(a)(6) (now § 211.194(b)) suggested that the word "significant" be inserted before "modification" to preclude the necessity of validating a minor change, such as glassware.

The Commissioner rejects this suggestion. If a method, when developed, published, and adopted, describes a procedure to be followed and types of materials to be used in its application, then any deviation from the prescribed procedures or materials may invalidate the results.

491. Comments on §§ 211.194 (c) and (d) (proposed as §§ 211.194(b) and 211.194(c), respectively) recommended substituting the word "adequate" for "complete" or deleting the word "complete" because these sections do not detail the criteria for the content of the records.

The Commissioner rejects these recommendations because the word "complete" is intended to require that the records contain all the generated data of all of the tests performed to assure that the laboratory reference standards, reagents, and standard solutions are suitable for use and that periodic calibration of pertinent equipment was accomplished. The Commissioner believes that it is not feasible to list in detail all the tests or procedures to be performed.

492. Several comments suggested deletion of the phrase "apparatus, gauges, and recording devices," and others recommended deletion of the word "apparatus," in both §§ 211.160(b) and 211.194(d). One comment said this requirement, as stated, could be interpreted by FDA investigators as including beakers, hot plates, and pipette washers.

The Commissioner notes that § 211.194(d) cites § 211.160(b)(4), which requires the calibration of instruments, apparatus, gauges, and recording devices at suitable intervals. In the case of pipettes, for example, it would not be suitable to calibrate at intervals since under normal conditions of use their capacity does not fluctuate. The Commissioner also recognizes that some equipment and apparatus cannot be calibrated, in which case the requirement obviously does not apply.

493. Comments on § 211.194(e) (proposed as § 211.194(d)) pointed out that § 211.166 only requires stability testing of drug products, not components or in-process materials; therefore, the record retention provisions of § 211.194(e) should apply only to stability testing of drug products.

The Commissioner agrees that the recordkeeping requirement of § 211.194(e) is intended to apply to stability testing performed in accordance with § 211.166, and the final regulation is revised accordingly. The Commissioner advises, however, that where stability testing of components or in-process materials is conducted, for example, as a part of the testing program to assess the stability characteristics of the drug product under § 211.166, the records of such stability testing are appropriately included under § 211.194(e).

DISTRIBUTION RECORDS

494. Several comments suggested that § 211.196 be revised to provide that information required by this section be readily retrievable.

The Commissioner notes that this is provided for in § 211.150(b). There is no need to repeat such a provision in this section.

495. One comment on § 211.196 said the lot or control number is not necessary because recalls can be accomplished by contacting every customer.

The Commissioner does not believe that reliance on this system of contacting every customer in case of recall is sound. Under such a system recalls could be delayed if customers who received recalled products were not contacted because they were not customers at the time of initiation of the recall. Conversely, customers who never received the product could be contacted, thus taxing the resources of the firm and FDA. A blanket recall might also cause unneeded patient anxiety and even drug shortages. Additionally, the Commissioner does not believe that the same accountability for each lot is inherent in a system that relies on contacting every customer. The amount of a recalled product that each customer received may be necessary information if the danger to health is severe enough to require that each unit of a recalled drug product be accounted for.

496. One comment on § 211.196 questioned the necessity for a lot number on distribution records being main-

tained by suppliers of compressed medical gas.

The Commissioner strongly believes that the requirements of this section should apply to compressed medical gas fillers. Compressed medical gases are potent drug products and, for example, a mixup in labeling of cylinders could constitute a most serious health problem. It could be imperative that every cylinder of a particular lot be accounted for. The Commissioner realizes that usually, compressed medical gases are distributed within a relatively small geographical area and to a limited number of customers, but this is not a sufficient reason to exempt suppliers from the requirements of this section. The requirements of § 211.196 should not constitute a major burden on this industry in view of the limited number of customers that are typically serviced by one establishment.

497. One comment on § 211.196 questioned the appropriateness of a customer code number on the distribution record in place of the customer's name and address if there is a breakdown of the code.

The Commissioner would deem the use of this type of system to be in compliance with the requirements of this section as long as adequate controls are employed to insure the accuracy of the code and legibility on the distribution record.

COMPLAINT FILES

498. Many comments addressed § 211.198(a). The comments mostly objected to designation of the quality control unit for reviewing all complaints.

The Commissioner has considered the extensive objections and concludes that revisions are necessary to clarify the intended requirements regarding complaint files. As indicated in the preamble to the February 13, 1976, proposal, the object is to specify more clearly how complaints regarding drug products are to be handled. It is not FDA's intention to restrict or limit review of such complaints to any one unit in the firm's organization, but to assure that the quality control unit is properly involved. Where there is a complaint involving the possible failure of a drug product to meet any of its specifications, the quality control unit is probably the most appropriate unit to determine whether an investigation under the procedures described in § 211.192 is required.

To provide manufacturers with as much latitude as possible for efficient review of drug product complaints, the final regulations provide that written procedures for handling complaints include review by the quality control unit where there is a possible failure of a drug product to meet its specifications.

The final regulations also provide that in such instances the quality control unit shall make a determination as to the need for an investigation in accordance with § 211.192. This provision allows judgment in determining the extent of the investigation. To safeguard against perfunctory review of complaints, § 211.198(b) requires a statement of the rationale for determining that no investigation is necessary and the identity of the person making that determination.

499. The comments regarding the recordkeeping provisions of § 211.198(b) objected primarily to the proposed requirement that companies that have more than one establishment maintain a copy of each complaint record at the establishment where the drug product involved was manufactured, processed, or packed (but not necessarily at every establishment where held only). A number of firms indicated that reports of complaints are currently centralized at one location, which often is the headquarters office. The comments were that duplicate records required at several locations would be confusing, and it would be difficult to be certain that every such record is complete. The comments also cited increased use of electronic and/or mechanical systems at central locations to store and retrieve data and records.

The Commissioner finds that some revisions in the proposed requirements are justified. He recognizes that many firms with multifacility operations depend on centralized systems to analyze, review, and even investigate complaints involving drug products. Therefore, the final regulations provide that the file designated for written records of drug product complaints may be at a central location provided that the written records are available for inspection. Where an investigation under § 211.192 is actually conducted, § 211.180(c) requires that records or copies of records of the investigation be readily available at the establishment where the activities described in the records occurred. This means that a record of an investigation conducted under § 211.192 must be maintained at the establishment where conducted, but that other records (e.g., of a medical investigation) regarding the drug product complaint may be maintained at a central location. The Commissioner believes that the provisions of § 211.198 will provide sufficient information regarding complaints about drug products that can be identified as to the point of manufacture.

Where no investigation under § 211.192 is conducted for a drug product complaint, the final regulations require, as was proposed, that the written complaint record include the reason that no investigation is necessary and the name of the responsible person making such a determination. Because no investigation under § 211.192 will have been conducted, and, in some cases, the point of manufacture cannot be ascertained, the Commissioner finds that the written record or a copy of it may be maintained at the place of manufacture, if known, or alternatively at a facility where it would be readily available for inspection.

500. Many comments objected to the 2-year retention requirement for records under § 211.198.

The record retention period is revised in line with other sections.

XVI. RETURNED AND SALVAGED DRUG PRODUCTS, RETURNED DRUG PRODUCTS

501. A number of comments said § 211.204 implies that a returned drug product must either be destroyed or reprocessed; an argument was made that reshipment of goods "as is" should not be excluded as a possibility.

The Commissioner does not believe that the section as worded excludes the possibility of reshipment "as is." As it applies to destruction or reprocessing, § 211.204 concerns returned drug products that have been held, stored, or shipped, before or during their return, under conditions that cast doubt on their integrity. This section does not prohibit reshipment without reprocessing of a drug product if its integrity was never in doubt, or if initially in doubt, subsequent investigations prove the drug product satisfactory. To preclude the possibility of misinterpretation, however, the Commissioner is revising this section in the final regulation.

502. One comment recommended that reshipment of returned drug products to charitable organizations should be exempt from the requirement in § 211.204 for recording quantities or lot numbers.

The Commissioner does not believe that shipments of drug products to charitable organizations should be any less controlled than drug products shipped to other categories of consumers.

503. Several comments said bioavailability is merely one facet of drug quality, and there is no need to mention it separately in § 211.204. Another comment said mentioning bioavailability is inappropriate for CGMP regulations.

The Commissioner finds that bioavailability is only one facet of drug quality and finds that it is unnecessary to mention only one of many facets that could be listed.

504. One comment on § 211.204 said the only true measure of bioavailability is in vivo testing and that in vivo

testing of returned goods is neither current practice nor realistic.

The Commissioner notes that bioavailability testing is not necessarily a requirement for releasing returned goods. If conditions were such that doubt was cast on a drug product's bioavailability, then suitable bioavailability testing would be required before the returned product could be released for distribution. Tests for bioavailability other than in vivo testing are recognized by FDA as valid in appropriate cases.

505. Several comments argued that the recordkeeping provisions of § 211.204 are unnecessary, redundant, and unduly costly for many operations.

The Commissioner does not agree with this position. He does not believe such recordkeeping to be unduly burdensome. This section does not require separate records for returned goods containing all the information required by this section, but rather requires firms to be able to identify which, if any, drug products have been returned and for what reason, and to be able to determine their disposition. The section would not prevent, for example, the disposition portion of the records on returned goods from being a part of normal distribution records if the lot involved were reshipped.

The Commissioner does not agree that the requirements for returned goods are unnecessary. For example, a portion of a lot of drug product may be returned because of unusual shipping conditions and the rest of the lot remain in normal trade channels. If the returned portion of the lot were destroyed and no record were made, there would be an incomplete record of distribution for the lot. In the case of recall, for example, a part of the lot could not be accounted for.

506. One comment on § 211.204 said a record of the lot number and other required information need not be retained in the case of returned goods that are destroyed.

The Commissioner rejects this comment. Accountability could not be accomplished in determining the distribution of a lot of drug product if destroyed products were exempt from this requirement.

507. One comment on § 211.204 recommended that time limits be established for destruction or reworking a returned drug product—a maximum 30-day time limit if destruction is the course of action, and 60 days if it is reprocessed.

The Commissioner finds no justification for establishing such arbitrary time limits. That processing must not go beyond appropriate limits is adequately covered elsewhere in these regulations.

508. One comment on § 211.204 noted that the reason for the return was omitted from the items to be included in the records.

The Commissioner believes that the reason for return is of primary importance and should be specifically included in this section. Therefore, the section is revised accordingly in the final regulations.

DRUG PRODUCT SALVAGING

The drug product salvaging provisions of these regulations were proposed on two separate occasions—in the FEDERAL REGISTER of January 16, 1975 and February 13, 1976. The comments discussed here include those received after both proposals were published.

509. One comment said § 211.208 could be interpreted as applying also to in-process materials unless further specified. It suggested that the title of the heading be changed to "Packaged Drug Product Salvaging."

The Commissioner finds there is no suggestion that this section applies to in-process materials. The section clearly refers to drug products, and that term is defined in § 210.3. The control of in-process materials, also defined in § 210.3(b), is covered elsewhere in Part 211.

510. One comment argued that § 211.208 is contradictory in that it prohibits salvaging and return of drug products to the marketplace, and then permits such procedures.

The Commissioner disagrees with this comment. The section prohibits the salvaging of drug products and/or return to the marketplace when the drug products have been exposed to improper storage conditions. The purpose of this section is to provide for an appropriate procedure for determining the suitability of salvaging drug products that may have been exposed to such conditions. The Commissioner believes that this section is adequately worded to convey its meaning.

511. Another comment recommended that the wording of § 211.208 be changed to allow manufacturers to determine what testing accurately reflects the condition of the product.

The Commissioner rejects this comment. The requirements of this section are the minimum procedures necessary to assure the safety and quality of drug products that may have been exposed to improper storage conditions.

512. A comment said it is unclear when § 211.208 applies and when § 211.204, "Returned Drug Products" is applicable.

The applicability of these sections depends on the history of the drug product. Section 211.204 is revised to require that the reason for return be included in the records pertaining to the returned drug. If the drug product is being returned because of possible exposure to improper conditions, the drug product salvaging requirements of § 211.208 must also be applied. The Commissioner believes that both sections clearly state their intent.

513. One comment said the phrase "evidence that the product meets all applicable standards of identity, strength, quality, and purity" should be deleted throughout § 211.208 because it is unnecessarily detailed and restrictive.

The Commissioner does not understand how the requirement that a drug product meets all applicable standards of identity, strength, quality, and purity could reasonably be considered either too detailed or too restrictive. Anything less would not assure the quality and safety of the drug product or that the product was not adulterated under the act. Therefore, the comment is rejected.

514. A number of comments on § 211.208 expressed concern that manufacturers and/or distributors do not have absolute control over a drug once it leaves their premises, and without evidence of proper control, drugs could not be returned under the proposed regulations, even in the normal course of a firm's business. They cited examples such as returning overstocked items, drugs which were ordered or distributed in error, seasonal items, re-certified antibiotics, or drugs requiring relabeling.

The Commissioner finds that the CGMP regulations do not prohibit drug products; being returned. The regulations clearly allow redistribution of returned drug products that meet applicable standards of safety, identity, strength, quality, and purity. If there is no question whether the drug products have been properly stored after leaving the manufacturer's control, the testing requirements of § 211.208 do not apply.

515. Three comments concerned the interpretation of "prolonged storage" in § 211.208. One comment recommended that this term be deleted; another recommended that it be revised to specify a period of time. One comment assumed that a 5-year maximum is preferred by FDA and could be a basis for defining "prolonged storage."

The Commissioner finds that, in view of the requirements regarding expiration dating of drug products, the proposed reference to prolonged storage in § 211.208 is unnecessary. The Commissioner concludes that this section should be further revised for simplicity, by referring to "improper storage conditions" rather than "improper storage or abnormal environmental conditions."

516. One comment on § 211.208 recommended that organoleptic examina-

tions be considered acceptable as evidence, provided such a determination is made by a pharmacist or chemist having 1 year's experience in the field.

Organoleptic examinations alone would never be enough to insure that a drug has maintained its strength, purity, and quality after it has been in a situation where it may have been exposed to improper storage conditions. Therefore, this comment cannot be accepted.

517. One comment recommended that § 211.208 provide for reclaiming of active ingredients from drug products that have been salvaged.

The Commissioner finds that drug products that have been subjected to improper storage conditions should not be salvaged because of the resulting questionable integrity of the drug product. Therefore, such drug products are clearly not suitable for reprocessing, including reclaiming of active ingredients. However, where salvaging is permissible under the provisions of § 211.208, any appropriate reprocessing is allowed. The Commissioner believes the regulations are clear in this regard.

XVII. CGMP FOR CERTAIN OTHER DRUG PRODUCTS

518. No comments or objections addressed proposed revocation of § 229.25. Section 229.25 is the only section contained in Part 229 (21 CFR Part 229), and the Commissioner sees no immediate need for retaining that part as currently used. Therefore, the entire Part 229 is revoked in these final regulations and reserved for future use.

The Commissioner has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 505, 506, 507, 510, 512, 701, 52 Stat. 1049-1053 as amended, 1055-1056 as amended, 59 Stat. 463 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351 (21 U.S.C. 351, 352, 355, 356, 357, 360, 360b, 371)) and the Drug Listing Act of 1972 (Pub. L. 92-387; 86 Stat. 559-562) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 201—LABELING

1. By revising § 201.17 to read as follows:

§ 201.17 Drugs; location of expiration date.

When an expiration date of a drug is required, e.g., expiration dating of drug products required by § 211.137 of this chapter, it shall appear on the immediate container and also the outer package, if any, unless it is easily legible through such outer package. However, when single-dose containers are packed in individual cartons, the expiration date may properly appear on the individual carton instead of the immediate product container.

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

2. By revising paragraph (b) and adding new paragraph (k) in § 207.3 to read as follows:

§ 207.3 Definitions.

* * * * *

(b) "Establishment" means a place of business under one management at one general physical location. The term includes, among others, independent laboratories that engage in control activities for registered drug establishments (e.g., "consulting" laboratories), manufacturers of medicated feeds and of vitamin products that are "drugs" within the meaning of section 201(g) of the act, human blood donor centers, animal facilities used for the production or control testing of licensed human biologicals, and establishments engaged in drug product salvaging.

* * * * *

(k) "Drug product salvaging" is the act of segregating drug products that may have been subjected to improper storage conditions such as extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation for the purpose of returning some or all of the products to the marketplace.

§ 207.20 [Amended]

3. By amending § 207.20 *Who must register and submit a drug list* in Subpart B of Part 207 by adding a comma and the phrase "nor is drug listing required for establishments engaged in drug product salvaging" before the period at the end of paragraph (a).

PART 210—CURRENT GOOD MANUFACTURING PRACTICES IN MANUFACTURING, PROCESSING, PACKING, OR HOLDING OF DRUGS: GENERAL

4. By revising Part 210 to read as follows:

Sec.
210.1 Status of current good manufacturing practice regulations.
210.2 Applicability of current good manufacturing practice regulations.
210.3 Definitions.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049-1050 as amended, 1055-1056 as amended (21 U.S.C. 351, 371).

§ 210.1 Status of current good manufacturing practice regulations.

(a) The regulations set forth in this part and in Parts 211 through 229 of this chapter contain the minimum current good manufacturing practice for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug to assure that such drug meets the requirements of the act as to safety, and has the identity and strength and meets the quality and purity characteristics that it purports or is represented to possess.

(b) The failure to comply with any regulation set forth in this part and in Parts 211 through 229 of this chapter in the manufacture, processing, packing, or holding of a drug shall render such drug to be adulterated under section 501(a)(2)(B) of the act and such drug, as well as the person who is responsible for the failure to comply, shall be subject to regulatory action.

§ 210.2 Applicability of current good manufacturing practice regulations.

(a) The regulations in this part and in Parts 211 through 229 of this chapter as they may pertain to a drug and in Parts 600 through 680 of this chapter as they may pertain to a biological product for human use, shall be considered to supplement, not supersede, each other, unless the regulations explicitly provide otherwise. In the event that it is impossible to comply with all applicable regulations in these parts, the regulations specifically applicable to the drug in question shall supersede the more general.

(b) If a person engages in only some operations subject to the regulations in this part and in Parts 211 through 229 and Parts 600 through 680 of this chapter, and not in others, that person need only comply with those regulations applicable to the operations in which he or she is engaged.

§ 210.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the

act shall be applicable to such terms when used in this part and in Parts 211 through 229 of this chapter.

(b) The following definitions of terms apply to this part and to Parts 211 through 229 of this chapter.

(1) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 301 et seq.).

(2) "Batch" means a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

(3) "Component" means any ingredient intended for use in the manufacture of a drug product, including those that may not appear in such drug product.

(4) "Drug product" means a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients. The term also includes a finished dosage form that does not contain an active ingredient but is intended to be used as a placebo.

(5) "Fiber" means any particulate contaminant with a length at least three times greater than its width.

(6) "Non-fiber-releasing filter" means any filter, which after any appropriate pretreatment such as washing or flushing, will not release fibers into the component or drug product that is being filtered. All filters composed of asbestos are deemed to be fiber-releasing filters.

(7) "Active ingredient" means any component that is intended to furnish pharmocological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure of any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect.

(8) "Inactive ingredient" means any component other than an "active ingredient."

(9) "In-process material" means any material fabricated, compounded, blended, or derived by chemical reaction that is produced for, and used in, the preparation of the drug product.

(10) "Lot" means a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

(11) "Lot number, control number, or batch number" means any distinctive combination of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacture, processing, packing, holding, and distribution of a batch or lot of drug product or other material can be determined.

(12) "Manufacture, processing, packing, or holding of a drug product" includes packaging and labeling operations, testing, and quality control of drug products.

(13) "Medicated feed" means any "complete feed," "feed supplement," or "feed concentrate" as defined in § 558.3 of this chapter and is a feed that contains one or more drugs as defined in section 201(g) of the act. Medicated feeds are subject to Part 225 of this chapter.

(14) "Medicated premix" means a substance that meets the definition in § 558.3 of this chapter for a "feed premix," except that it contains one or more drugs as defined in section 201(g) of the act and is intended for manufacturing use in the production of a medicated feed. Medicated premixes are subject to Part 226 of this chapter.

(15) "Quality control unit" means any person or organizational element designated by the firm to be responsible for the duties relating to quality control.

(16) "Strength" means:

(i) The concentration of the drug substance (for example, weight/weight, weight/volume, or unit dose/volume basis), and/or

(ii) The potency, that is, the therapeutic activity of the drug product as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard).

(17) "Theoretical yield" means the quantity that would be produced at any appropriate phase of manufacture, processing, or packing of a particular drug product, based upon the quantity of components to be used, in the absence of any loss or error in actual production.

(18) "Actual yield" means the quantity that is actually produced at any appropriate phase of manufacture, processing, or packing of a particular drug product.

(19) "Percentage of theoretical yield" means the ratio of the actual yield (at any appropriate phase of manufacture, processing, or packing of a particular drug product) to the theoretical yield (at the same phase), stated as a percentage.

(20) "Acceptance criteria" means the product specifications and acceptance/rejection criteria, such as acceptable quality level and unacceptable quality level, with an associated sampling plan, that are necessary for making a decision to accept or reject a lot or batch (or any other convenient subgroups of manufactured units).

(21) "Representative sample" means a sample that consists of a number of units that are drawn based on rational criteria such as random sampling and intended to assure that the sample accurately portrays the material being sampled.

PART 211—CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

5. By revising Part 211 to read as follows:

Subpart A—General Provisions

Sec.
211.1 Scope.
211.3 Definitions.

Subpart B—Organization and Personnel

211.22 Responsibilities of quality control unit.
211.25 Personnel qualifications.
211.28 Personnel responsibilities.
211.34 Consultants.

Subpart C—Buildings and Facilities

211.42 Design and construction features.
211.44 Lighting.
211.46 Ventilation, air filtration, air heating and cooling.
211.48 Plumbing.
211.50 Sewage and refuse.
211.52 Washing and toilet facilities.
211.56 Sanitation.
211.58 Maintenance.

Subpart D—Equipment

Sec.
211.63 Equipment design, size, and location.
211.65 Equipment construction.
211.67 Equipment cleaning and maintenance.
211.68 Automatic, mechanical, and electronic equipment.
211.72 Filters.

Subpart E—Control of Components and Drug Product Containers and Closures

211.80 General requirements.
211.82 Receipt and storage of untested components, drug product containers, and closures.
211.84 Testing and approval or rejection of components, drug product containers, and closures.
211.86 Use of approved components, drug product containers, and closures.
211.87 Retesting of approved components, drug product containers, and closures.
211.89 Rejected components, drug product containers, and closures.
211.94 Drug product containers and closures.

Subpart F—Production and Process Controls

211.100 Written procedures; deviations.
211.101 Charge-in of components.
211.103 Calculation of yield.

211.105 Equipment identification.
211.110 Sampling and testing of in-process materials and drug products.
211.111 Time limitations on production.
211.113 Control of microbiological contamination.
211.115 Reprocessing.

Subpart G—Packaging and Labeling Control

211.122 Materials examination and usage criteria.
211.125 Labeling issuance.
211.130 Packaging and labeling operations.
211.134 Drug product inspection.
211.137 Expiration dating.

Subpart H—Holding and Distribution

211.142 Warehousing procedures.
211.150 Distribution procedures.

Subpart I—Laboratory Controls

211.160 General requirements.
211.165 Testing and release for distribution.
211.166 Stability testing.
211.167 Special testing requirements.
211.170 Reserve samples.
211.173 Laboratory animals.
211.176 Penicillin contamination.

Subpart J—Records and Reports

211.180 General requirements.
211.182 Equipment cleaning and use log.
211.184 Component, drug product container, closure, and labeling records.
211.186 Master production and control records.
211.188 Batch production and control records.
211.192 Production record review.
211.194 Laboratory records.
211.196 Distribution records.
211.198 Complaint files.

Subpart K—Returned and Salvaged Drug Products

211.204 Returned drug products.
211.208 Drug product salvaging.

AUTHORITY: Secs. 501, 701, 52 Stat. 1049–1050 as amended, 1055–1056 as amended (21 U.S.C. 351, 371).

Subpart A—General Provisions

§ 211.1 Scope.

(a) The regulations in this part contain the minimum current good manufacturing practice for preparation of drug products for administration to humans or animals.

(b) The current good manufacturing practice regulations in this chapter, as they pertain to drug products, and in Parts 600 through 680 of this chapter, as they pertain to biological products for human use, shall be considered to supplement, not supersede, the regulations in this part unless the regulations explicitly provide otherwise. In the event it is impossible to comply with applicable regulations both in this part and in other parts of this chapter or in Parts 600 through 680 of this chapter, the regulation specifically applicable to the drug product in question shall supersede the regulation in this part.

(c) Pending consideration of a proposed exemption, published in the FEDERAL REGISTER of November 29, 1978, the requirements in this part shall not be enforced for OTC drug products if the products and all their ingredients are ordinarily marketed and consumed as human foods, and which products may also fall within the legal definition of drugs by virtue of their intended use. Therefore, until further notice, regulations under Part 110 of this chapter, and where applicable, Parts 113 to 129 of this chapter, shall be applied in determining whether these OTC drug products that are also foods are manufactured, processed, packed, or held under current good manufacturing practice.

§ 211.3 Definitions.

The definitions set forth in § 210.3 of this chapter apply in this part.

Subpart B—Organization and Personnel

§ 211.22 Responsibilities of quality control unit.

(a) There shall be a quality control unit that shall have the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated. The quality control unit shall be responsible for approving or rejecting drug products manufactured, processed, packed, or held under contract by another company.

(b) Adequate laboratory facilities for the testing and approval (or rejection) of components, drug product containers, closures, packaging materials, in-process materials, and drug products shall be available to the quality control unit.

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

(d) The responsibilities and procedures applicable to the quality control unit shall be in writing; such written procedures shall be followed.

§ 211.25 Personnel qualifications.

(a) Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs and in current good manufacturing practice (including the current good manufacturing practice regulations in this chapter and written procedures required by these regulations) as they relate to the employee's functions. Training in current good manufacturing practice shall be conducted by qualified individuals on a continuing basis and with sufficient frequency to assure that employees remain familiar with CGMP requirements applicable to them.

(b) Each person responsible for supervising the manufacture, processing, packing, or holding of a drug product shall have the education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the drug product has the safety, identity, strength, quality, and purity that it purports or is represented to possess.

(c) There shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product.

§ 211.28 Personnel responsibilities.

(a) Personnel engaged in the manufacture, processing, packing, or holding of a drug product shall wear clean clothing appropriate for the duties they perform. Protective apparel, such as head, face, hand, and arm coverings, shall be worn as necessary to protect drug products from contamination.

(b) Personnel shall practice good sanitation and health habits.

(c) Only personnel authorized by supervisory personnel shall enter those areas of the buildings and facilities designated as limited-access areas.

(d) Any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesions that may adversely affect the safety or quality of drug products shall be excluded from direct contact with components, drug product containers, closures, in-process materials, and drug products until the condition is corrected or determined by competent medical personnel not to jeopardize the safety or quality of drug products. All personnel shall be instructed to report to supervisory personnel any health conditions that may have an adverse effect on drug products.

§ 211.34 Consultants.

Consultants advising on the manufacture, processing, packing, or holding of drug products shall have sufficient education, training, and experience, or any combination thereof, to advise on the subject for which they are retained. Records shall be maintained stating the name, address, and

qualifications of any consultants and the type of service they provide.

Subpart C—Buildings and Facilities

§ 211.42 Design and construction features.

(a) Any building or buildings used in the manufacture, processing, packing, or holding of a drug product shall be of suitable size, construction and location to facilitate cleaning, maintenance, and proper operations.

(b) Any such building shall have adequate space for the orderly placement of equipment and materials to prevent mixups between different components, drug product containers, closures, labeling, in-process materials, or drug products, and to prevent contamination. The flow of components, drug product containers, closures, labeling, in-process materials, and drug products through the building or buildings shall be designed to prevent contamination.

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas for the firm's operations to prevent contamination or mixups as follows:

(1) Receipt, identification, storage, and withholding from use of components, drug product containers, closures, and labeling, pending the appropriate sampling, testing, or examination by the quality control unit before release for manufacturing or packaging;

(2) Holding rejected components, drug product containers, closures, and labeling before disposition;

(3) Storage of released components, drug product containers, closures, and labeling;

(4) Storage of in-process materials;

(5) Manufacturing and processing operations;

(6) Packaging and labeling operations;

(7) Quarantine storage before release of drug products;

(8) Storage of drug products after release;

(9) Control and laboratory operations;

(10) Aseptic processing, which includes as appropriate:

(i) Floors, walls, and ceilings of smooth, hard surfaces that are easily cleanable;

(ii) Temperature and humidity controls;

(iii) An air supply filtered through high-efficiency particulate air filters under positive pressure, regardless of whether flow is laminar or nonlaminar;

(iv) A system for monitoring environmental conditions;

(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;

(vi) A system for maintaining any equipment used to control the aseptic conditions.

(d) Operations relating to the manufacture, processing, and packing of penicillin shall be performed in facilities separate from those used for other drug products for human use.

§ 211.44 Lighting.

Adequate lighting shall be provided in all areas.

§ 211.46 Ventilation, air filtration, air heating and cooling.

(a) Adequate ventilation shall be provided.

(b) Equipment for adequate control over air pressure, micro-organisms, dust, humidity, and temperature shall be provided when appropriate for the manufacture, processing, packing, or holding of a drug product.

(c) Air filtration systems, including prefilters and particulate matter air filters, shall be used when appropriate on air supplies to production areas. If air is recirculated to production areas, measures shall be taken to control recirculation of dust from production. In areas where air contamination occurs during production, there shall be adequate exhaust systems or other systems adequate to control contaminants.

(d) Air-handling systems for the manufacture, processing, and packing of penicillin shall be completely separate from those for other drug products for human use.

§ 211.48 Plumbing.

(a) Potable water shall be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any drug product. Potable water shall meet the standards prescribed in the Public Health Service Drinking Water Standards set forth in Subpart J of 42 CFR Part 72. Water not meeting such standards shall not be permitted in the potable water system.

(b) Drains shall be of adequate size and, where connected directly to a sewer, shall be provided with an air break or other mechanical device to prevent back-siphonage.

§ 211.50 Sewage and refuse.

Sewage, trash, and other refuse in and from the building and immediate premises shall be disposed of in a safe and sanitary manner.

§ 211.52 Washing and toilet facilities.

Adequate washing facilities shall be provided, including hot and cold water, soap or detergent, air driers or single-service towels, and clean toilet facilities easily accesible to working areas.

§ 211.56 Sanitation.

(a) Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a clean and sanitary condition. Any such building shall be free of infestation by rodents, birds, insects, and other vermin (other than laboratory animals). Trash and organic waste matter shall be held and disposed of in a timely and sanitary manner.

(b) There shall be written procedures assigning responsibility for sanitation and describing in sufficient detail the cleaning schedules, methods, equipment, and materials to be used in cleaning the buildings and facilities; such written procedures shall be followed.

(c) There shall be written procedures for use of suitable rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents. Such written procedures shall be designed to prevent the contamination of equipment, components, drug product containers, closures, packaging, labeling materials, or drug products and shall be followed. Rodenticides, insecticides, and fungicides shall not be used unless registered and used in accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 135).

(d) Sanitation procedures shall apply to work performed by contractors or temporary employees as well as work performed by full-time employees during the ordinary course of operations.

§ 211.58 Maintenance.

Any building used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair.

Subpart D—Equipment

§ 211.63 Equipment design, size, and location.

Equipment used in the manufacture, processing, packing, or holding of a drug product shall be of appropriate design, adequate size, and suitably located to facilitate operations for its intended use and for its cleaning and maintenance.

§ 211.65 Equipment construction.

(a) Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Any substances required for operation, such as lubricants or coolants, shall not come into contact with com-

ponents, drug product containers, closures, in-process materials, or drug products so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

§ 211.67 Equipment cleaning and maintenance.

(a) Equipment and utensils shall be cleaned, maintained, and sanitized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

(b) Written procedures shall be established and followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing, or holding of a drug product. These procedures shall include, but are not necessarily limited to, the following:

(1) Assignment of responsibility for cleaning and maintaining equipment;

(2) Maintenance and cleaning schedules, including, where appropriate, sanitizing schedules;

(3) A description in sufficient detail of the methods, equipment, and materials used in cleaning and maintenance operations, and the methods of disassembling and reassembling equipment as necessary to assure proper cleaning and maintenance;

(4) Removal or obliteration of previous batch identification;

(5) Protection of clean equipment from contamination prior to use;

(6) Inspection of equipment for cleanliness immediately before use.

(c) Records shall be kept of maintenance, cleaning, sanitizing, and inspection as specified in §§ 211.180 and 211.182.

§ 211.68 Automatic, mechanical, and electronic equipment.

(a) Automatic, mechanical, or electronic equipment or other types of equipment, including computers, or related systems that will perform a function satisfactorily, may be used in the manufacture, processing, packing, and holding of a drug product. If such equipment is so used, it shall be routinely calibrated, inspected, or checked according to a written program designed to assure proper performance. Written records of those calibration checks and inspections shall be maintained.

(b) Appropriate controls shall be exercised over computer or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel. Input to and output from the computer or related system of formulas or other records or data shall be checked for accuracy. A backup file of data entered into the computer or related system shall be maintained except where certain data, such as calculations performed in connection with laboratory analysis, are eliminated by computerization or other automated processes. In such instances a written record of the program shall be maintained along with appropriate validation data. Hard copy or alternative systems, such as duplicates, tapes, or microfilm, designed to assure that backup data are exact and complete and that it is secure from alteration, inadvertent erasures, or loss shall be maintained.

§ 211.72 Filters.

Filters for liquid filtration used in the manufacture, processing, or packing of injectable drug products intended for human use shall not release fibers into such products. Fiber-releasing filters may not be used in the manufacture, processing, or packing of these injectable drug products unless it is not possible to manufacture such drug products without the use of such filters. If use of a fiber-releasing filter is necessary, an additional non-fiber-releasing filter of 0.22 micron maximum mean porosity (0.45 micron if the manufacturing conditions so dictate) shall subsequently be used to reduce the content of particles in the injectable drug product. Use of an asbestos-containing filter, with or without subsequent use of a specific non-fiber-releasing filter, is permissible only upon submission of proof to the appropriate bureau of the Food and Drug Administration that use of a non-fiber-releasing filter will, or is likely to, compromise the safety or effectiveness of the injectable drug product.

Subpart E—Control of Components and Drug Product Containers and Closures

§ 211.80 General requirements.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, testing, and approval or rejection of components and drug product containers and closures; such written procedures shall be followed.

(b) Components and drug product containers and closures shall at all times be handled and stored in a manner to prevent contamination.

(c) Bagged or boxed components or drug product containers, or closures shall be stored off the floor and suitably spaced to permit cleaning and inspection.

(d) Each container or grouping of containers for components or drug product containers, or closures shall be identified with a distinctive code for each lot in each shipment received. This code shall be used in recording the disposition of each lot. Each lot shall be appropriately identified as to its status (i.e., quarantined, approved, or rejected).

§ 211.82 Receipt and storage of untested components, drug product containers, and closures.

(a) Upon receipt and before acceptance, each container or grouping of containers of components, drug product containers, and closures shall be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination.

(b) Components, drug product containers, and closures shall be stored under quarantine until they have been tested or examined, as appropriate, and released. Storage within the area shall conform to the requirements of § 211.80.

§ 211.84 Testing and approval or rejection of components, drug product containers, and closures.

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

(b) Representative samples of each shipment of each lot shall be collected for testing or examination. The number of containers to be sampled, and the amount of material to be taken from each container, shall be based upon appropriate criteria such as statistical criteria for component variability, confidence levels, and degree of precision desired, the past quality history of the supplier, and the quantity needed for analysis and reserve where required by § 211.170.

(c) Samples shall be collected in accordance with the following procedures:

(1) The containers of components selected shall be cleaned where necessary, by appropriate means.

(2) The containers shall be opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, drug product containers, or closures.

(3) Sterile equipment and aseptic sampling techniques shall be used when necessary.

(4) If it is necessary to sample a component from the top, middle, and bottom of its container, such sample subdivisions shall not be composited for testing.

(5) Sample containers shall be identified so that the following information can be determined: name of the material sampled, the lot number, the container from which the sample was

taken, the data on which the sample was taken, and the name of the person who collected the sample.

(6) Containers from which samples have been taken shall be marked to show that samples have been removed from them.

(d) Samples shall be examined and tested as follows:

(1) At least one test shall be conducted to verify the identity of each component of a drug product. Specific identify tests, if they exist, shall be used.

(2) Each component shall be tested for conformity with all appropriate written specifications for purity, strength, and quality. In lieu of such testing by the manufacturer, a report of analysis may be accepted from the supplier of a component, provided that at least one specific identity test is conducted on such component by the manufacturer, and provided that the manufacturer establishes the reliability of the supplier's analyses through appropriate validation of the supplier's test results at appropriate intervals.

(3) Containers and closures shall be tested for conformance with all appropriate written procedures. In lieu of such testing by the manufacturer, a certificate of testing may be accepted from the supplier, provided that at least a visual identification is conducted on such containers/closures by the manufacturer and provided that the manufacturer establishes the reliability of the supplier's test results through appropriate validation of the supplier's test results at appropriate intervals.

(4) When appropriate, components shall be microscopically examined.

(5) Each lot of a component, drug product container, or closure that is liable to contamination with filth, insect infestation, or other extraneous adulterant shall be examined against established specifications for such contamination.

(6) Each lot of a component, drug product container, or closure that is liable to microbiological contamination that is objectionable in view of its intended use shall be subjected to microbiological tests before use.

(e) Any lot of components, drug product containers, or closures that meets the appropriate written specifications of identity, strength, quality, and purity and related tests under paragraph (d) of this section may be approved and released for use. Any lot of such material that does not meet such specifications shall be rejected.

§ 211.86 Use of approved components, drug product containers, and closures.

Components, drug product containers, and closures approved for use shall be rotated so that the oldest approved stock is used first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

§ 211.87 Retesting of approved components, drug product containers, and closures.

Components, drug product containers, and closures shall be retested or reexamined, as appropriate, for identity, strength, quality, and purity and approved or rejected by the quality control unit in accordance with § 211.84 as necessary, e.g., after storage for long periods or after exposure to air, heat or other conditions that might adversely affect the component, drug product container, or closure.

§ 211.89 Rejected components, drug product containers, and closures.

Rejected components, drug product containers, and closures shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

§ 211.94 Drug product containers and closures.

(a) Drug product containers and closures shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug beyond the official or established requirements.

(b) Container closure systems shall provide adequate protection against foreseeable external factors in storage and use that can cause deterioration or contamination of the drug product.

(c) Drug product containers and closures shall be clean and, where indicated by the nature of the drug, sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

(d) Standards or specifications, methods of testing, and, where indicated, methods of cleaning, sterilizing, and processing to remove pyrogenic properties shall be written and followed for drug product containers and closures.

Subpart F—Production and Process Controls

§ 211.100 Written procedures; deviations.

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

(b) Written production and process control procedures shall be followed in the execution of the various production and process control functions and shall be documented at the time of performance. Any deviation from the written procedures shall be recorded and justified.

§ 211.101 Charge-in of components.

Written production and control procedures shall include the following, which are designed to assure that the drug products produced have the identity, strength, quality, and purity they purport or are represented to possess:

(a) The batch shall be formulated with the intent to provide not less than 100 percent of the labeled or established amount of active ingredient.

(b) Components for drug product manufacturing shall be weighed, measured, or subdivided as appropriate. If a component is removed from the original container to another, the new container shall be identified with the following information:

(1) Component name or item code;

(2) Receiving or control number;

(3) Weight or measure in new container;

(4) Batch for which component was dispensed, including its product name, strength, and lot number.

(c) Weighing, measuring, or subdividing operations for components shall be adequately supervised. Each container of component dispensed to manufacturing shall be examined by a second person to assure that:

(1) The component was released by the quality control unit;

(2) The weight or measure is correct as stated in the batch production records;

(3) The containers are properly identified.

(d) Each component shall be added to the batch by one person and verified by a second person.

§ 211.103 Calculation of yield.

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall be performed by one person and independently verified by a second person.

§ 211.105 Equipment identification.

(a) All compounding and storage containers, processing lines, and major equipment used during the production of a batch of a drug product shall be properly identified at all times to indicate their contents and, when necessary, the phase of processing of the batch.

(b) Major equipment shall be identified by a distinctive identification number or code that shall be recorded in the batch production record to show the specific equipment used in the manufacture of each batch of a drug product. In cases where only one of a particular type of equipment exists in a manufacturing facility, the name of the equipment may be used in lieu of a distinctive identification number or code.

§ 211.110 Sampling and testing of in-process materials and drug products.

(a) To assure batch uniformity and integrity of drug products, written procedures shall be established and followed that describe the in-process controls, and tests, or examinations to be conducted on appropriate samples of in-process materials of each batch. Such control procedures shall be established to monitor the output and to validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product. Such control procedures shall include, but are not limited to, the following, where appropriate:

(1) Tablet or capsule weight variation;

(2) Disintegration time;

(3) Adequacy of mixing to assure uniformity and homogeneity;

(4) Dissolution time and rate;

(5) Clarity, completeness, or pH of solutions.

(b) Valid in-process specifications for such characteristics shall be consistent with drug product final specifications and shall be derived from previous acceptable process average and process variability estimates where possible and determined by the application of suitable statistical procedures where appropriate. Examination and testing of samples shall assure that the drug product and in-process material conform to specifications.

(c) In-process materials shall be tested for identity, strength, quality, and purity as appropriate, and approved or rejected by the quality control unit, during the production process, e.g., at commencement or completion of significant phases or after storage for long periods.

(d) Rejected in-process materials shall be identified and controlled under a quarantine system designed to prevent their use in manufacturing or processing operations for which they are unsuitable.

§ 211.111 Time limitations on production.

When appropriate, time limits for the completion of each phase of production shall be established to assure the quality of the drug product. Deviation from established time limits may be acceptable if such deviation does not compromise the quality of the drug product. Such deviation shall be justified and documented.

§ 211.113 Control of microbiological contamination.

(a) Appropriate written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, shall be established and followed.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of any sterilization process.

§ 211.115 Reprocessing.

(a) Written procedures shall be established and followed prescribing a system for reprocessing batches that do not conform to standards or specifications and the steps to be taken to insure that the reprocessed batches will conform with all established standards, specifications, and characteristics.

(b) Reprocessing shall not be performed without the review and approval of the quality control unit.

Subpart G—Packaging and labeling Control

§ 211.122 Materials examination and usage criteria.

(a) There shall be written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials; such written procedures shall be followed. Labeling and packaging materials shall be representatively sampled, and examined or tested upon receipt and before use in packaging or labeling of a drug product.

(b) Any labeling or packaging materials meeting appropriate written specifications may be approved and released for use. Any labeling or packaging materials that do not meet such specifications shall be rejected to prevent their use in operations for which they are unsuitable.

(c) Records shall be maintained for each shipment received of each different labeling and packaging material indicating receipt, examination or testing, and whether accepted or rejected.

(d) Labels and other labeling materials for each different drug product, strength, dosage form, or quantity of contents shall be stored separately with suitable identification. Access to the storage area shall be limited to authorized personnel.

(e) Obsolete and outdated labels, labeling, and other packaging materials shall be destroyed.

(f) Gang printing of labeling to be used for different drug products or different strengths of the same drug product (or labeling of the same size and identical or similar format and/or color schemes) shall be minimized. If gang printing is employed, packaging and labeling operations shall provide for special control procedures, taking into consideration sheet layout, stacking, cutting, and handling during and after printing.

(g) Printing devices on, or associated with, manufacturing lines used to imprint labeling upon the drug product unit label or case shall be monitored to assure that all imprinting conforms to the print specified in the batch production record.

§ 211.125 Labeling issuance.

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations.

(b) Labeling materials issued for a batch shall be carefully examined for identity and conformity to the labeling specified in the master or batch production records.

(c) Procedures shall be utilized to reconcile the quantities of labeling issued, used, and returned, and shall require evaluation of discrepancies found between the quantity of drug product finished and the quantity of labeling issued when such discrepancies are outside narrow preset limits based on historical operating data. Such discrepancies shall be investigated in accordance with § 211.192.

(d) All excess labeling bearing lot or control numbers shall be destroyed.

(e) Returned labeling shall be maintained and stored in a manner to prevent mixups and provide proper identification.

(f) Procedures shall be written describing in sufficient detail the control procedures employed for the issuance of labeling; such written procedures shall be followed.

§ 211.130 Packaging and labeling operations.

There shall be written procedures designed to assure that correct labels, labeling, and packaging materials are used for drug products; such written procedures shall be followed. These procedures shall incorporate the following features:

(a) Prevention of mixups and cross-contamination by physical or spatial separation from operations on other drug products.

(b) Identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch.

(c) Examination of packaging and labeling materials for suitability and correctness before packaging oper-

ations, and documentation of such examination in the batch production record.

(d) Inspection of the packaging and labeling facilities immediately before use to assure that all drug products have been removed from previous operations. Inspection shall also be made to assure that packaging and labeling materials not suitable for subsequent operations have been removed. Results of inspection shall be documented in the batch production records.

§ 211.134 Drug product inspection.

(a) Packaged and labeled products shall be examined during finishing operations to provide assurance that containers and packages in the lot have the correct label.

(b) A representative sample of units shall be collected at the completion of finishing operations and shall be visually examined for correct labeling.

(c) Results of these examinations shall be recorded in the batch production or control records.

§ 211.137 Expiration dating.

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

(b) Expiration dates shall be related to any storage conditions stated on the labeling, as determined by stability studies described in § 211.166.

(c) If the drug product is to be reconstituted at the time of dispensing, its labeling shall bear expiration information for both the reconstituted and unreconstituted drug products.

(d) Expiration dates shall appear on labeling in accordance with the requirements of § 201.17 of this chapter.

(e) Homeopathic drug products shall be exempt from the requirements of this section.

(f) Pending consideration of a proposed exemption, published in the FEDERAL REGISTER of September 29, 1978, the requirements in this section shall not be enforced for human OTC drug products if their labeling does not bear dosage limitations and they are stable for at least 3 years as supported by appropriate stability data.

Subpart H—Holding and Distribution

§ 211.142 Warehousing procedures.

Written procedures describing the warehousing of drug products shall be established and followed. They shall include:

(a) Quarantine of drug products before release by the quality control unit.

(b) Storage of drug products under appropriate conditions of temperature, humidity, and light so that the identity, strength, quality, and purity of the drug products are not affected.

§ 211.150 Distribution procedures.

Written procedures shall be established, and followed, describing the distribution of drug products. They shall include:

(a) A procedure whereby the oldest approved stock of a drug product is distributed first. Deviation from this requirement is permitted if such deviation is temporary and appropriate.

(b) A system by which the distribution of each lot of drug product can be readily determined to facilitate its recall if necessary.

Subpart I—Laboratory Controls

§ 211.160 General requirements.

(a) The establishment of any specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms required by this subpart, including any change in such specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms, shall be drafted by the appropriate organizational unit and reviewed and approved by the quality control unit. The requirements in this subpart shall be followed and shall be documented at the time of performance. Any deviation from the written specifications, standards, sampling plans, test procedures, or other laboratory control mechanisms shall be recorded and justified.

(b) Laboratory controls shall include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components, drug product containers, closures, in-process materials, labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity. Laboratory controls shall include:

(1) Determination of conformance to appropriate written specifications for the acceptance of each lot within each shipment of components, drug product containers, closures, and labeling used in the manufacture, processing, packing, or holding of drug products. The specifications shall include a description of the sampling and testing procedures used. Samples shall be representative and adquately identified. Such procedures shall also require appropriate retesting of any component, drug product container, or closure that is subject to deterioration.

(2) Determination of conformance to written specifications and a description of sampling and testing procedures for in-process materials. Such samples shall be representative and properly identified.

(3) Determination of conformance to written descriptions of sampling procedures and appropriate specifications for drug products. Such samples shall be representative and properly identified.

(4) The calibration of instruments, apparatus, gauges, and recording devices at suitable intervals in accordance with an established written program containing specific directions, schedules, limits for accuracy and precision, and provisions for remedial action in the event accuracy and/or precision limits are not met. Instruments, apparatus, gauges, and recording devices not meeting established specifications shall not be used.

§ 211.165 Testing and release for distribution.

(a) For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. Where sterility and/or pyrogen testing are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed as soon as possible.

(b) There shall be appropriate laboratory testing, as necessary, of each batch of drug product required to be free of objectionable microorganisms.

(c) Any sampling and testing plans shall be described in written procedures that shall include the method of sampling and the number of units per batch to be tested; such written procedure shall be followed.

(d) Acceptance criteria for the sampling and testing conducted by the quality control unit shall be adequate to assure that batches of drug products meet each appropriate specification and appropriate statistical quality control criteria as a condition for their approval and release. The statistical quality control criteria shall include appropriate acceptance levels and/or appropriate rejection levels.

(e) The accurancy, sensitivity, specificity, and reproducibility of test methods employed by the firm shall be established and documented. Such validation and documentation may be accomplished in accordance with § 211.194(a)(2).

(f) Drug products failing to meet established standards or specifications and any other relevant quality control criteria shall be rejected. Reprocessing may be performed. Prior to acceptance and use, reprocessed material must meet appropriate standards, specifications, and any other relevant critieria.

§ 211.166 Stability testing.

(a) There shall be a written testing program designed to assess the stabil-

ity characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

(b) An adequate number of batches of each drug product shall be tested to determine an appropriate expiration date and a record of such data shall be maintained. Accelerated studies, combined with basic stability information on the components, drug products, and container-closure system, may be used to support tentative expiration dates provided full shelf life studies are not available and are being conducted. Where data from accelerated studies are used to project a tentative expiration date that is beyond a date supported by actual shelf life studies, there must be stability studies conducted, including drug product testing at appropriate intervals, until the tentative expiration date is verified or the appropriate expiration date determined.

(c) For homeopathic drug products, the requirements of this section are as follows:

(1) There shall be a written assessment of stability based at least on testing or examination of the drug product for compatibility of the ingredients, and based on marketing experience with the drug product to indicate that there is no degradation of the product for the normal or expected period of use.

(2) Evaluation of stability shall be based on the same container-closure system in which the drug product is being marketed.

§ 211.167 Special testing requirements.

(a) For each batch of drug product purporting to be sterile and/or pyrogen-free, there shall be appropriate laboratory testing to determine conformance to such requirements. The test procedures shall be in writing and shall be followed.

(b) For each batch of ophthalmic ointment, there shall be appropriate testing to determine conformance to specifications regarding the presence of foreign particles and harsh or abrasive substances. The test procedures shall be in writing and shall be followed.

(c) For each batch of controlled-release dosage form, there shall be appropriate laboratory testing to determine conformance to the specifications for the rate of release of each active ingredient. The test procedures shall be in writing and shall be followed.

§ 211.170 Reserve samples.

(a) An appropriately identified reserve sample representative of each lot in each shipment of each active ingredient shall be retained for at least 1 year after the expiration date of the last lot of the drug product containing the active ingredient or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last drug product lot containing the active ingredient. It shall consist of at least twice the quantity necessary for all tests required to determine whether the active ingredient meets its established specifications, except the quantity requirement shall not apply for sterility and pyrogen samples.

(b) A properly identified reserve sample representative of each lot or batch of drug product shall be stored under conditions consistent with product labeling and shall be retained for at least 1 year after the expiration date of the drug product or in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the lot or batch of drug product. The sample shall be stored in the same immediate container-closure system in which the drug product is marketed or an immediate container-closure system having essentially the same characteristics. The sample shall consist of at least twice the quantity necessary to perform all the required tests, except those for sterility and pyrogens. Such samples shall be at least visually examined annually for evidence of deterioration unless such examination would affect the integrity of the samples. The results of such examination shall be recorded and maintained with other stability data on the drug product. Samples of compressed medical gases need not be retained.

§ 211.173 Laboratory animals.

Animals used in testing components, in-process materials, or drug products for compliance with established specifications shall be maintained and controlled in a manner that assures their suitability for their intended use. They shall be identified, and adequate records shall be maintained showing the history of their use.

§ 211.176 Penicillin contamination.

If a reasonable possibility exists that a non-penicillin drug product has been exposed to cross-contamination with penicillin, the non-penicillin drug product shall be tested for the presence of penicillin. Such drug product shall not be marketed if detectable levels are found when tested according to procedures specified in "Procedures for Detecting and Measuring Penicillin Contamination in Drugs." [1]

Subpart J—Records and Reports

§ 211.180 General requirements.

(a) Any production, control, or distribution record that is required to be maintained in compliance with this part and is specifically associated with a batch of a drug product shall be retained for at least 1 year after the expiration date of the batch or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the batch.

(b) Records shall be maintained for all components, drug product containers, closures, and labeling for at least 1 year after the expiration date or, in the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, 3 years after distribution of the last lot of drug product incorporating the component or using the container, closure, or labeling.

(c) All records required under this part, or copies of such records, shall be readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred. These records or copies thereof shall be subject to photocopying or other means of reproduction as part of such inspection. Records that can be immediately retrieved from another location by computer or other electronic means shall be considered as meeting the requirements of this paragraph.

(d) Records required under this part may be retained either as original records or as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records. Where reduction techniques, such as microfilming, are used, suitable reader and photocopying equipment shall be readily available.

(e) Written records required by this part shall be maintained so that data therein can be used for evaluating, at least annually, the quality standards of each drug product to determine the need for changes in drug product specifications or manufacturing or

[1] Copies may be obtained from: Director, NCAA (HFD-430), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204.

control procedures. Written procedures shall be established and followed for such evaluations and shall include provisions for:

(1) A review of every batch, whether approved or rejected, and, where applicable, records associated with the batch.

(2) A review of complaints, recalls, returned or salvaged drug products, and investigations conducted under § 211.192 for each drug product.

(f) Procedures shall be established to assure that the responsible officials of the firm, if they are not personally involved in or immediately aware of such actions, are notified in writing of any investigations conducted under §§ 211.198, 211.204, or 211.208 of these regulations, any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to good manufacturing practices brought by the Food and Drug Administration.

§ 211.182 Equipment cleaning and use log.

A written record of major equipment cleaning, maintenance (except routine maintenance such as lubrication and adjustments), and use shall be included in individual equipment logs that show the date, time, product, and lot number of each batch processed. If equipment is dedicated to manufacture of one product, then individual equipment logs are not required, provided that lots or batches of such product follow in numerical order and are manufactured in numerical sequence. In cases where dedicated equipment is employed, the records of cleaning, maintenance, and use shall be part of the batch record. The persons performing and double-checking the cleaning and maintenance shall date and sign or initial the log indicating that the work was performed. Entries in the log shall be in chronological order.

§ 211.184 Component, drug product container, closure, and labeling records.

These records shall include the following:

(a) The identity and quantity of each shipment of each lot of components, drug product containers, closures, and labeling; the name of the supplier; the supplier's lot number(s) if known; the receiving code as specified in § 211.80; and the date of receipt. The name and location of the prime manufacturer, if different from the supplier, shall be listed if known.

(b) The results of any test or examination performed (including those performed as required by § 211.82(a), § 211.84(d), or § 211.122(a)) and the conclusions derived therefrom.

(c) An individual inventory record of each component, drug product container, and closure and, for each component, a reconciliation of the use of each lot of such component. The inventory record shall contain sufficient information to allow determination of any batch or lot of drug product associated with the use of each component, drug product container, and closure.

(d) Documentation of the examination and review of labels and labeling for conformity with established specifications in accord with §§ 211.122(c) and 211.130(c).

(e) The disposition of rejected components, drug product containers, closure, and labeling.

§ 211.186 Master production and control records.

(a) To assure uniformity from batch to batch, master production and control records for each drug product, including each batch size thereof, shall be prepared, dated, and signed (full signature, handwritten) by one person and independently checked, dated, and signed by a second person. The preparation of master production and control records shall be described in a written procedure and such written procedure shall be followed.

(b) Master production and control records shall include:

(1) The name and strength of the product and a description of the dosage form;

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit;

(3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;

(4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records;

(5) A statement concerning any calculated excess of component;

(6) A statement of theoretical weight or measure at appropriate phases of processing;

(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to § 211.192 is required;

(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;

(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

§ 211.188 Batch production and control records.

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

(1) Dates;

(2) Identity of individual major equipment and lines used;

(3) Specific identification of each batch of component or in-process material used;

(4) Weights and measures of components used in the course of processing;

(5) In-process and laboratory control results;

(6) Inspection of the packaging and labeling area before and after use;

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(8) Complete labeling control records, including specimens or copies of all labeling used;

(9) Description of drug product containers and closures;

(10) Any sampling performed;

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation;

(12) Any investigation made according to § 211.192.

(13) Results of examinations made in accordance with § 211.134.

§ 211.192 Production record review.

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has alrady been distributed. The investigation shall extend to other batches of the same drug product and

other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

§ 211.194 Laboratory records.

(a) Laboratory records shall include complete data derived from all tests necessary to assure compliance with established specifications and standards, including examinations and assays, as follows:

(1) A description of the sample received for testing with identification of source (that is, location from where sample was obtained), quantity, lot number or other distinctive code, date sample was taken, and date sample was received for testing.

(2) A statement of each method used in the testing of the sample. The statement shall indicate the location of data that establish that the methods used in the testing of the sample meet proper standards of accuracy and reliability as applied to the product tested. (If the method employed is in the current revision of the United States Pharmacopeia, National Formulary, Association of Official Analytical Chemists, Book of Methods,[2] or in other recognized standard references, or is detailed in an approved new drug application and the referenced method is not modified, a statement indicating the method and reference will suffice). The suitability of all testing methods used shall be verified under actual conditions of use.

(3) A statement of the weight or measure of sample used for each test, where appropriate.

(4) A complete record of all data secured in the course of each test, including all graphs, charts, and spectra from laboratory instrumentation, properly identified to show the specific component, drug product container, closure, in-process material, or drug product, and lot tested.

(5) A record of all calculations performed in connection with the test, including units of measure, conversion factors, and equivalency factors.

(6) A statement of the results of tests and how the results compare with established standards of identity, strength, quality, and purity for the component, drug product container, closure, in-process material, or drug product tested.

(7) The initials or signature of the person who performs each test and the date(s) the tests were performed.

(8) The initials or signature of a second person showing that the original records have been reviewed for accuracy, completeness, and compliance with established standards.

(b) Complete records shall be maintained of any modification of an established method employed in testing. Such records shall include the reason for the modification and data to verify that the modification produced results that are at least as accurate and reliable for the material being tested as the established method.

(c) Complete records shall be maintained of any testing and standardization of laboratory reference standards, reagents, and standard solutions.

(d) Complete records shall be maintained of the periodic calibration of laboratory instruments, apparatus, gauges, and recording devices required by § 211.160(b)(4).

(e) Complete records shall be maintained of all stability testing performed in accordance with § 211.166.

§ 211.196 Distribution records.

Distribution records shall contain the name and strength of the product and a description of the dosage form, name and address of the consignee, date and quantity shipped, and lot or control number of the drug product.

§ 211.198 Complaint files.

(a) Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed. Such procedures shall include provisions for review by the quality control unit, of any complaint involving the possible failure of a drug product to meet any of its specifications and, for such drug products, a determination as to the need for an investigation in accordance with § 211.192.

(b) A written record of each complaint shall be maintained in a file designated for drug product complaints. The file regarding such drug product complaints shall be maintained at the establishment where the drug product involved was manufactured, processed, or packed, or such file may be maintained at another facility if the written records in such files are readily available for inspection at that other facility. Written records involving a drug product shall be maintained until at least 1 year after the expiration date of the drug product, or 1 year after the date that the complaint was received, whichever is longer. In the case of certain OTC drug products lacking expiration dating because they meet the criteria for exemption under § 211.137, such written records shall be maintained for 3 years after distribution of the drug product.

(1) The written record shall include the following information, where known: the name and strength of the drug product, lot number, name of complainant, nature of complaint, and reply to complainant.

(2) Where an investigation under § 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with § 211.180(c).

(3) Where an investigation under § 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

Subpart K—Returned and Salvaged Drug Products

§ 211.204 Returned drug products.

Returned drug products shall be identified as such and held. If the conditions under which returned drug products have been held, stored, or shipped before or during their return, or if the condition of the drug product, its container, carton, or labeling, as a result of storage or shipping, casts doubt on the safety, identity, strength, quality or purity of the drug product, the returned drug product shall be destroyed unless examination, testing, or other investigations prove the drug product meets appropriate standards of safety, identity, strength, quality, or purity. A drug product may be reprocessed provided the subsequent drug product meets appropriate standards, specifications, and characteristics. Records of returned drug products shall be maintained and shall include the name and label potency of the drug product dosage form, lot number (or control number or batch number), reason for the return, quantity returned, date of disposition, and ultimate disposition of the returned drug product. If the reason for a drug product being returned implicates associated batches, an appropriate investigation shall be conducted in accordance with the requirements of § 211.192. Procedures for the holding, testing, and reprocessing of returned drug products shall be in writing and shall be followed.

§ 211.208 Drug product salvaging.

Drug products that have been subjected to improper storage conditions including extremes in temperature, humidity, smoke, fumes, pressure, age, or radiation due to natural disasters, fires, accidents, or equipment failures shall not be salvaged and returned to the marketplace. Whenever there is a question whether drug products have been subjected to such conditions, salvaging operations may be conducted only if there is (a) evidence from labo-

[2] Copies may be obtained from: Association of Official Analytical Chemists, P.O. Box 540, Benjamin Franklin Station, Washington, D.C. 20204.

ratory tests and assays (including animal feeding studies where applicable) that the drug products meet all applicable standards of identity, strength, quality, and purity and (b) evidence from inspection of the premises that the drug products and their associated packaging were not subjected to improper storage conditions as a result of the disaster or accident. Organoleptic examinations shall be acceptable only as supplemental evidence that the drug products meet appropriate standards of identity, strength, quality, and purity. Records including name, lot number, and disposition shall be maintained for drug products subject to this section.

PART 229—CURRENT GOOD MANUFACTURING PRACTICE FOR CERTAIN OTHER DRUG PRODUCTS

§ 229.25 [Revoked]

6. By revoking § 229.25 and thereby revoking Part 229.

Effective date. This regulation shall be effective on March 1, 1979. The expiration dating requirements under these amendments and not previously in effect shall apply to drug products manufactured after that date.

(Secs. 501, 502, 505, 506, 507, 510, 701, 52 Stat. 1049-1053 as amended, 59 Stat. 463 as amended, 76 Stat. 794 as amended (21 U.S.C. 351, 352, 355, 356, 357, 360, 371); Pub. L. 92-387, 86 Stat. 559-562.).

Dated: September 15, 1979.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

NOTE.—Incorporation by reference materials approved by the Director of the Office of the Federal Register on March 11, 1976 (footnote 2) and October 21, 1977 (footnote 1). Copies of referenced materials are on file at the FEDERAL REGISTER library.

[FR Doc. 78-27121 Filed 9-22-78; 12:43 pm]

[4110-03]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 211]

[Docket No. 78N-0140]

HUMAN AND VETERINARY DRUGS; CURRENT GOOD MANUFACTURING PRACTICE FOR DRUG PRODUCTS

Exemptions for Certain OTC Drug Products

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: Based on comments received in response to proposed changes in current good manufacturing practice regulations for drugs, the agency is proposing two additional provisions as follows: (1) An exemption from required expiration dating for human over-the-counter (OTC) drug products that are marketed without dosage limitations and are stable for at least 3 years; and (2) an exemption providing for OTC drug products that are ordinarily marketed and consumed as human foods and that may also fall within the legal definition of drugs by virtue of their intended use to be inspected under good manufacturing practice regulations for foods rather than such regulations for drugs. Until final regulations under this proposal are published, manufacturers may continue to market without expiration dates human OTC drug products that meet the proposed definitions. Similarly, until final regulations are adopted, good manufacturing practice regulations for foods will be applied to OTC drug products that are ordinarily marketed and consumed as human foods and that may also fall within the legal definition of drugs by virtue of their intended use.

DATE: Comments by November 28, 1978.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Clifford G. Broker (HFD-323) (301-443-5307), or Robert J. Rice, Jr., (HFD-30) (301-443-5220), Bureau of Drugs, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: Elsewhere in this issue of the FEDERAL REGISTER, the Commissioner of Food and Drugs is issuing final regulations for current good manufacturing practice (CGMP) for human and veterinary drug products. They are being adopted after careful consideration of extensive comments from the public, including consumers, regulated industry, and health care professionals, in response to a proposal published in the FEDERAL REGISTER of February 13, 1976 (41 FR 6878). In light of those comments, the Commissioner concluded that there was sufficient reason to reconsider whether all human OTC drug products should bear an expiration date and whether OTC drug products that are ordinarily marketed and consumed as human foods and that may also fall within the legal definition of drugs by virtue of their intended use are more appropriately inspected under good manufacturing practice regulations for foods rather than those for drugs. To fully consider these issues, the Commissioner has delayed implementing certain requirements under Part 211 (21 CFR Part 211) until comments on this proposal can be evaluated and final regulations published.

OTC DRUG PRODUCTS WITHOUT DOSAGE LIMITATIONS

As discussed in the preamble to the final regulations for Part 211, a substantial number of comments were received concerning a proposed requirement that all drug products bear an expiration date. Many comments, particularly those from certain segments of the human OTC drug industry, suggested that some drug products are so safe and are consumed so quickly that expiration dating would be unnecessary for them. Respondents suggested as examples of such human OTC drug products medicated shampoos and topical lotions, creams, and ointments, fluoride toothpaste, and rubbing alcohol. Many persons objected to expiration dating for these classes of human OTC drug products on the basis that adding such information to immediate containers and outer retail packages was not cost-effective in relationship to the benefit derived by the consumer.

The Commissioner recognizes that many human OTC drug products are safe and suitable for frequent and often prolonged use. Such products are marketed without dosage limitations and, typically, the contents of the retail package are used in a relatively short time. He believes that, given the high market volume of these types of preparations, their safety, and the speed with which they are usually used, the advantages of expiration dating to the consumer may not be worth the added cost, which is ultimately borne by the consumer. Therefore, the Commissioner considers it reasonable to propose to exempt human OTC drug products that have no dosage limitations from the expiration dating requirements of § 211.137.

In considering the desirability of exempting any class of drugs from expiration dating, the Commissioner is concerned that drug products that may be unstable are routinely in the marketplace and may not be fully consumed before deterioration occurs. For example, significant stability problems have been noted with some fluoride toothpastes. Therefore, to minimize the possibility that human OTC drug products with relatively short periods of stability are permitted to be marketed without expiration dating, the Commissioner proposes that, as a condition for exemption, the drug product must be shown to be stable for at least 3 years. The 3-year time period is proposed on the assumption that most drug products of this type will be used by consumers well within the 3-year period. The Commissioner notes that one comment to the February 13, 1976 CGMP proposal stated that, based on information regarding a leading medicated shampoo, there is a 95 percent probability that all of a batch of the preparation is consumed within 83 weeks (1.6 years). Several other comments also suggested that a specific time period of stability (e.g. 3 or 5 years) would be appropriate for determining whether to require an expiration date for certain human OTC drug products.

The Commissioner is limiting the proposed exemption under § 211.137 to human OTC drug products because he believes that it is inappropriate for veterinary drug products. The veterinary drug industry differs significantly in nature and scope from the human drug industry. Many of the veterinary drug products available for OTC sale contain active ingredients that would cause these products to bear the prescription legend if labeled for human use. Examples of such veterinary drug products are topical sulfonamides, nitrofurans, neomycin sulfate, oxytetracycline, hydrocortisone, and polymyxin B. Consumers must be assured that these drug products are of sufficient potency to achieve their intended therapeutic effect for animal care.

The Commissioner believes that OTC veterinary drug products that are stable for at least 3 years and that are labeled without dosage limitations are likely to remain in distribution channels longer than OTC human drug products that meet the same criteria. During this distribution period, such veterinary drug products may be exposed to adverse storage conditions, such as those encountered in some feed stores, that may affect their stability.

OTC DRUG PRODUCTS ORDINARILY MARKETED AND CONSUMED AS HUMAN FOODS THAT MAY ALSO FALL WITHIN THE LEGAL DEFINITION OF DRUGS BY VIRTUE OF THEIR INTENDED USE

The Commissioner has tentatively concluded that a few products ordinarily consumed as human foods, but also marketed as drugs, would be more appropriately regulated under good manufacturing practice regulations for foods, i.e., 21 CFR Part 110 and, if appropriate, 21 CFR Parts 113 through 129. Therefore, he proposes to exempt from Part 211, OTC drug products that are also human foods, if they are ordinarily consumed as human foods and if all their ingredients are ordinarily consumed as human foods. Examples of products that the Commissioner believes would be covered by the proposed exemption are (1) some candy cough drops that are formulated entirely of ingredients ordinarily consumed as human foods or ingredients of human food products; and (2) sodium bicarbonate labeled for use as an antacid, but ordinarily used as an ingredient of human foods under the more common "baking soda" label.

In proposing this exemption for drugs that are also human foods, the Commissioner has considered, first, the inadvisability of applying drug CGMP regulations that are not necessary to assure appropriate quality characteristics in view of the intended use of a product and, second, the reasonableness of applying human food GMP regulations to a product manufactured, handled, and ordinarily consumed as a human food.

The Commissioner has considered the merits of applying an exemption from Part 211 to OTC drug products that are also animal foods, and that otherwise would meet the criteria for exemption. He has concluded that the CGMP's for human food are not suitable for determining compliance with current good manufacturing practice for certain types of animal food. He also notes that no existing CGPM regulations apply to animal feed. Therefore, the Commissioner has limited the proposed exemption from Part 211 to OTC drug products ordinarily consumed and marketed as human food and that otherwise meet the criteria for exemption in this FEDERAL REGISTER proposal.

The Commissioner especially invites comments on the desirability of providing these exemptions. He also requests comment on whether the classes of drug products proposed for exemption are adequately defined, particularly on the adequacy of at least a 3-year period of stability. He invites manufacturers to identify products that appear likely to be exempted under this proposal.

The Commissioner wishes to make clear that in proposing these exemptions for these types of products, he does not intend that the products be exempt from other provisions of the act and regulations that are applicable to drugs or drug products.

The Commissioner has determined that this document does not contain an agency action covered by 21 CFR 25.1(b), and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 505, 506, 507, 512, 701, 52 Stat. 1049–1053 as amended, 1055–1056 as amended, 55 Stat. 851, 59 Stat. 463 as amended, 82 Stat. 343–351 (21 U.S.C. 351, 352, 355, 356, 357, 360b, 371)) and under authority delegated to him (21 CFR 5.1), the Commissioner proposes to amend Part 211 as follows:

1. In § 211.1 by revising paragraph (c) to read as follows:

§ 211.1 Scope.

* * * * *

(c) OTC drug products ordinarily marketed and consumed as human foods that may also fall within the legal definition of drugs by virtue of their intended use: Drug products that meet these criteria shall be subject to Part 110 of this chapter, and where applicable, Parts 113 through 129 of this chapter, in determining whether such products are manufactured, processed, packed, or held in conformance with current good manufacturing practice.

2. In § 211.137 by revising paragraph (f) to read as follows:

§ 211.137 Expiration dating.

* * * * *

(f) Human OTC drug products are exempt from the requirements of this section if their labeling does not bear dosage limitation and they are stable for at least 3 years, as supported by appropriate stability data.

Interested persons may, on or before November 28, 1978, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, Md. 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. Assessment of the economic impact has been made in conjunction with the economic impact assessment of the final regulations for current good manufacturing practice for human and veterinary drugs (Docket No. 75N-0339) appearing elsewhere in this issue of the FEDERAL REGISTER. A copy of the economic impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Dated: September 15, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 78-27122 Filed 9-22-78; 12:43 pm]

federal register

FRIDAY, SEPTEMBER 29, 1978
PART III

DEPARTMENT OF LABOR

Employment Standards Administration

■

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

[4510-27]

DEPARTMENT OF LABOR

Employment Standards Administration

MINIMUM WAGES FOR FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION

General Wage Determination Decisions

General Wage Determination Decisions of the Secretary of Labor specify, in accordance with applicable law and on the basis of information available to the Department of Labor from its study of local wage conditions and from other sources, the basic hourly wage rates and fringe benefit payments which are determined to be prevailing for the described classes of laborers and mechanics employed in construction activity of the character and in the localities specified therein.

The determinations in these decisions of such prevailing rates and fringe benefits have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates, (37 FR 21138) and of Secretary of Labor's Orders 12-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in effective date as prescribed in that section, because the necessity to issue construction industry wage determination frequently and in large volume causes precedures to be impractical and contrary to the public interest.

General Wage Determination Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision together with any modifications issued subsequent to this publication date shall be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR, Part 5. The wage rates contained therein shall be the minimum paid under such contract by contractors and subcontractors on the work.

MODIFICATIONS AND SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and Supersedeas Decisions to General Wage Determination Decisions are based upon information obtained concerning changes in prevailing hourly wage rates and fringe benefit payments since the decisions were issued.

The determinations of prevailing rates and fringe benefits made in the Modifications and Supersedeas Decisions have been made by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR 1.1 (including the statutes listed at 36 FR 306 following Secretary of Labor's Order No. 24-70) containing provisions for the payment of wages which are dependent upon determination by the Secretary of Labor under the Davis-Bacon Act; and pursuant to the provisions of part 1 of subtitle A of Title 29 of Code of Federal Regulations, Procedure for Predetermination of Wage Rates (37 FR 21138) and of Secretary of Labor's Orders 13-71 and 15-71 (36 FR 8755, 8756). The prevailing rates and fringe benefits determined in foregoing General Wage Determination Decisions, as hereby modified, and/or superseded shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged in contract work of the character and in the localities described therein.

Modifications and Supersedeas Decisions are effective from their date of publication in the FEDERAL REGISTER without limitation as to time and are to be used in accordance with the provisions of 29 CFR Parts 1 and 5.

Any person, organization, or governmental agency having an interest in the wages determined as prevailing is encouraged to submit wage rate information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Office of Special Wage Standards, Division of Wage Determinations, Washington, D.C. 20210. The cause for not utilizing the rulemaking procedures prescribed in 5 U.S.C. 553 has been set forth in the original General Wage Determination Decision.

MODIFICATIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

California:	
CA78-5122	Aug. 11, 1978.
Colorado:	
CO78-5108; CA78-5109; CO78-5110; CA78-5111; CO78-5112.	July 14, 1978.
Connecticut:	
CT75-2067	Apr. 25, 1975.
CT78-3055; CT78-3056	July 28, 1978.
Illinois:	
IL28-2008	Feb. 17, 1978.
IL78-2071	Sept. 1, 1978.
Indiana:	
IL78-2008	Feb. 17, 1978.
IL78-2071	Sept. 1, 1978.
Kentucky:	
IL78-2008	Feb. 17, 1978.
Louisiana:	
LA78-4072	July 14, 1978.
LA78-4077	Aug. 11, 1978.
Michigan:	
IL78-2071	Sept. 1, 1978.
Minnesota:	
IL78-2071	Do.
Missouri:	
IL78-2008	Feb. 17, 1978.
New York:	
IL78-2071	Sept. 1, 1978.
Ohio:	
IL78-2008	Feb. 17, 1978.
I178-2071	Sept. 1, 1978.
Oregon:	
OR78-5104	June 30, 1978.
Pennsylvania:	
IL78-2071	Sept. 1, 1978.
Texas:	
TX78-4078; TX78-4079	Aug. 11, 1978.
TX78-4080	Aug. 4, 1978.
TX78-4088	Aug. 25, 1978.
Washington:	
WA78-5105	June 30, 1978.
Wisconsin:	
IL78-2071	Sept. 1, 1978.
West Virginia:	
IL78-2008	Feb. 17, 1978.

SUPERSEDEAS DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

The numbers of the decisions being modified and their dates of publication in the FEDERAL REGISTER are listed with each State.

Spersedeas decision numbers are in parentheses following the numbers of the decisions being superseded.

Florida:	
FL75-1104 (FL78-1084)	Oct. 24, 1975.
Michigan:	
MI78-2010 (MI78-2072); MI78-2011 (MI78-2073); MI78-2012 (MI78-2074); MI78-2013 (MI78-2075); MI78-2014 (MI78-2076); MI78-2015 (MI78-2077) MI78-2016 (MI78-2078).	Mar. 10, 1978.
Minnesota:	
MN77-2043 (MN78-2095); MN77-2044 (MN78-2096); MN77-2045 (MN78-2097); MN77-2046 (MN78-2098).	May 6, 1977.
MN78-2009 (MN78-2099)	Mar. 10, 1978.
North Carolina:	
NC77-1017 (NC78-1081)	Feb. 11, 1977.
Pennsylvania:	
PA77-3104 (PA78-3070)	July 22, 1977.
PA77-3121 (PA78-3068)	Sept. 9, 1977.
South Carolina:	
SC75-1079 (SC78-1085)	Sept. 5, 1975.

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

None.

Signed at Washington, D.C., this 22d day of September 1978.

DOROTHY P. COME,
Assistant Administrator, Wage and Hour Division.

DECISION NO. CA78-5122 - Mod.#1
(43 FR 35835 - August 11, 1978)
Imperial, Kern, Los Angeles, Orange, Riverside, San - Bernardino, San Luis Obispo, Santa Barbara and Ventura Counties, California

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
PLASTERERS' TENDERS:					
Imperial, Riverside and San Bernardino Counties	11.02	1.15	2.45		
REFRIGERATION & AIR CONDITIONING:					
Riverside and San Bernardino Counties	10.70	.96	.85	1.00	.05
ROOFERS:					
Imperial County	10.79	.80	1.05	1.00	
SHEET METAL WORKERS:					
Imperial County	13.96	1.04	2.24		.01

DECISION NO. C078-5108 - Mod. #1
(43 FR 30431 - July 14, 1978)
Statewide, Colorado

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Change:					
Carpenters:					
Carpenters					
*Zone I	$ 9.32	.80	.90	.75	.07
*Zone II	9.82	.80	.90	.75	.07
Underground Carpenters					
*Zone I	9.52	.80	.90	.75	.07
*Zone II	10.02	.80	.90	.75	.07
Working on creosoted coated lumber or other toxic materials, sawmen continuously assigned to 1½ HP at job site	9.62	.80	.90	.75	.07
High work 35' above ground or above permanent floor or deck	9.67	.80	.90	.75	.07
Cement Masons:					
*Zone I	9.40	.52	1.15	.30	.11
*Zone II	9.90	.52	1.15	.30	.11
Electricians:					
Alamosa, Archuleta, Baca, Bent, Chaffee, Crowley, Custer, Fremont, Huerfano, Kiowa, La Animas, Mineral, Otero, Prowers, Pueblo and Rio Grande Counties					
Zone I:					
Electricians	11.40	.72	3%+.80		1½%
Cable Splicers	12.54	.72	3%+.80		1½%
Zone II:					
Electricians	11.80	.72	3%+.80		1½%
Cable Splicers	12.94	.72	3%+.80		1½%
Zone III:					
Electricians	12.15	.72	3%+.80		1½%
Cable Splicers	13.29	.72	3%+.80		1½%
Zone IV:					
Electricians	13.28	.72	3%+.80		1½%
Cable Splicers	14.42	.72	3%+.80		1½%
Electricians on electrical contracts less than $20,000 in Zones III and IV	9.65	.72	3%+.80		1½%

MODIFICATIONS P. 3

DECISION NO. C078-5108 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Truck Drivers: Zones 1* and 2* - All Groups (1 thru 18) change - VACATION ONLY				.46	
Add:					
Power Equipment Operators:					
Group 1: Rodman, Chainman, Grade Checker	$ 8.75	.74	.90	.35	.06
Zone 1	$ 8.75	.74	.90	.35	.06
Zone 2	9.50	.74	.90	.35	.06
Group 3: Instrument Man					
Zone 1	9.45	.74	.90	.35	.06
Zone 2	10.20	.74	.90	.35	.06
DECISION NO. C078-5109 - Mod. #1 (43 FR 30437 - July 14, 1978) Adams, Arapahoe, Boulder, Clear Creek, Denver, Douglas, Eagle, Elbert, Gilpin, Grand, Jefferson, Lake, Larimer, Morgan, Park, Summit and Weld Counties, Colorado					
Change:					
Asbestos Workers	12.14	.55	$1.37		
Boilermakers	12.30	.85	1.00		.02
Bricklayers; Stonemasons:					
Eagle County	10.75	.85	.95		.05
Boulder and Grand Counties	9.80	.85	.95		.05
Elbert, Lake and Park Cos.	10.65	.85	.95		.05
Cement Masons:					
Cement Masons	10.68	.52	1.15		.11
Working with composition materials and color	11.18	.52	1.15		.11
Working on scaffold, swing stage, or temporary platform over 25'	10.92	.52	1.15		.11
Elevator Constructors	11.71	.895	.56	a	.025
Elevator Constructors' Helpers	70%JR	.895	.56	a	.025

MODIFICATIONS P. 4

DECISION NO. C078-5109 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Roofers: Remaining Counties including Northern portions of Lake, Park, Jefferson, Douglas and Elbert Counties	$10.47	.80	.50		.08
Footnote: a. Employer contributes 8% of basic hourly rate for over 5 years' service and 6% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.					
Truck Drivers: Zones 1* and 2* - All Groups (1 thru 18) Change- VACATION ONLY				.46	
Add:					
Power Equipment Operators:					
Group 1: Rodman, Chainman, Grade Checker					
Zone 1	8.75	.74	.90	.35	.06
Zone 2	9.50	.74	.90	.35	.06
Group 3: Instrument Man					
Zone 1	9.45	.74	.90	.35	.06
Zone 2	10.20	.74	.90	.35	.06
DECISION NO. C078-5110 - Mod. #1 (43 FR 30443 - July 14, 1978) El Paso County, Colorado					
Change:					
Asbestos Workers	$12.14	.55	$1.37		.02
Boilermakers	12.30	.85	1.00		.04
Bricklayers; Stonemasons	10.65	.85	.95		.04
Cement Masons:					
Cement Masons	10.68	.52	1.15		.11
Working with composition materials and color	11.18	.52	1.15		.11
Working on temporary platform over 25'	10.93	.52	1.15		.11
Elevator Constructors	11.71	.895	.56	a	.025
Elevator Constructors' Helpers	70%JR	.895	.56	a	.025
Roofers	9.93	.52	.40		
Footnote: a. Employer contributes 8% of basic hourly rate for over 5 years' service; 6% of basic hourly rate for 6 months to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.					

DECISION NO. CO78-5110 - Mod. #1

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Truck Drivers:					
Groups 1 thru 18 - Change- VACATION ONLY				.46	
Add:					
Power Equipment Operators:					
Group 1: Rodman, Chainman, Grade Checker	$8.75	.74	.90	.35	.06
Group 3: Instrument Man	9.45	.74	.90	.35	.06

DECISION NO. CO78-5111 - Mod. #1
(43 FR 30451 - July 14, 1978)
Delta, Garfield, Gunnison, Mesa, Montrose and Pitkin Counties, Colorado

Change:					
Asbestos Workers	$12.15	.55	$1.37		
Boilermakers	12.30	.85	1.00		.02
Bricklayers; Stonemasons: Remaining Counties	10.35	.85	.95		.05
Cement Masons:					
Cement Masons	10.68	.52	1.15		.11
Working with composition materials and color	11.18	.52	1.15		.11
Working on scaffold, swing stage or temporary platfrom over 25'	10.93	.52	1.15		.11
Elevator Constructors	11.71	.895	.56	a	.025
Elevator Constructors' Helpers	70%JR	.895	.56	a	.025
Millwrights	10.86	.80	.85		.13
Roofers	9.93	.52	.40		

Footnote: a. Employer contributes 8% of basic hourly rate for over 5 years' service and 6% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.

Truck Drivers:					
Zones 1* and 2* - All Groups (1 thrub 18) Change- VACATION ONLY				.46	

DECISION NO. CO78-5111 (Cont'd)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Add:					
Power Equipment Operators:					
Group 1: Rodmen; Chainman; Grade Checker					
Zone 1	$8.75	.74	.90	.35	.06
Zone 2	9.50	.74	.90	.35	.06
Group 3: Instrument Man					
Zone 1	9.45	.74	.90	.35	.06
Zone 2	10.20	.74	.90	.35	.06

DECISION NO. CO78-5112 - Mod. #1
(43 FR 30447 - July 14, 1978)
Las Animas, Otero and Pueblo Counties, Colorado

Change:					
Asbestos Workers	$12.14	.55	$1.37		
Boilermakers	12.30	.85	1.00		.02
Bricklayers	10.72	.85	.95		.07
Cement Masons:					
Cement Masons	10.68	.52	1.15		.11
Working with composition material and color	11.18	.52	1.15		.11
Working on scaffold, swing stage or temporaty platfrom over 25'	10.93	.52	1.15		.11
Electricians:					
Zone 1:					
Electricians	11.40	.72	3%+.80		1½%
Cable Splicers	12.54	.72	3%+.80		1½%
Zone II:					
Electricians	11.80	.72	3%+.80		1½%
Cable Splicers	12.94	.72	3%+.80		1½%
Zone III:					
Electricians	12.15	.72	3%+.80		1½%
Cable Splicers	13.29	.72	3%+.80		1½%
Zone IV:					
Electricians	13.28	.72	3%+.80		1½%
Cable Splicers	14.42	.72	3%+.80		1½%
Electrical contracts under $20,000 in Zones II, III & IV	9.65	.72	3%+.80		1½%
Elevator Constructors	11.71	.895	.56	a	.025

MODIFICATIONS P. 7

DECISION NO. CO78-5112 - (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Elevator Constructors' Helpers	70%JR	.895	.56	a	.025
Roofers	9.93	.52	.40		
Soft Floor Layers: Pueblo County	9.00	.40	.75	.30	.10
Footnote: a. Employer contributes 8% of basic hourly rate for over 5 years' service and 6% of basic hourly rate for 6 months' to 5 years' service as Vacation Pay Credit. Six Paid Holidays: A through F.					
Truck Drivers: Zones 1* and 2* - All Groups (1 thru 18) Change-- VACATION ONLY				.46	
Add: Power Equipment Operators Group 1: Rodman, Chainman, Grade Checker					
Zone 1	8.75	.74	.90	.35	.06
Zone 2	9.50	.74	.90	.35	.06
Group 3: Instrument Man					
Zone 1	9.45	.74	.90	.35	.06
Zone 2	10.20	.74	.90	.35	.06

MODIFICATIONS P. 8

DECISION #CT75-2067 - MOD. #2 (40 FR 18304 - April 25, 1975) Hartford County, Connecticut	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE: Residential Construction: Electricians: Berlin, Bristol, New Britain, Newington, Plainville, Southington	$10.80	1.00	3%+.52		½%
DECISION #CT78-3055 - MOD. #6 (43 FR 33023 - July 28, 1978) Fairfield, Litchfield and Windham Counties, Connecticut					
CHANGE: Electricians: Litchfield Co.: Plymouth Building Construction	$10.80	1.00	3%+.52		½%
DECISION #CT78-3056 - MOD. #4 (43 FR 33030 - July 28, 1978) Hartford, Middlesex, New Haven, New London, and Tolland Counties, Connecticut					
CHANGE: Electricians: Hartford Co.: Berlin, Bristol, New Britain, Newington, Plainville, and Southington Township	$10.80	1.00	3%+.52		½%

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #IL78-2008 - MOD. #1 (43 FR 7125 - February 17, 1978) Illinois, Indiana, Kentucky, Missouri, Ohio, and West Virginia					
ADD:					
Area IV					
Within the geographical jurisdiction of the St. Paul District Corps of Engineers					
Levermen, Engineer, Mechanic, and Boatman	$ 9.71	.95	.85		
Oiler	8.79	.95	.85		
Area V					
Within the geographical jurisdiction of the Rock Island District Corps of Engineers					
Levermen, Engineer, Mechanic and Boatman	10.48	.95	.85		
Oiler	8.86	.95	.85		
DECISION #IL78-2071 - MOD. #1 (43 FR 39260 - September 1, 1978) Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin					
CHANGE:					
Footnote:					
b. $7.20 per day, per employee					

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #LA78-4072 - Mod. #6 (43 FR 30456 - July 14, 1978) Bossier, Caddo & Calcasieu Parishes, Louisiana					
Omit:					
Painters (Bossier & Caddo Pars.):					
Group 1	$ 8.85	.40	.30		.05
Group 2	9.10	.40	.30		.05
Group 3	9.35	.40	.30		.05
Group 4	9.45	.40	.30		.05
Add:					
Painters (Bossier & Caddo Pars.):					
Painters, tape & float, vinyl & paperhangers & decorators	9.20	.40	.30		.05
DECISION #LA78-4077 - Mod. #4 (43 FR 35841 - August 11, 1978) Statewide Louisiana					
Omit:					
Painters:					
Zone 6:					
Group 1 - Painters, tape, float & paperhangers; stage, window jacks & structural steel	8.85	.40	.30		.05
Group 2 - Stage, window jacks & structural steel over 30 ft.	9.10	.40	.30		.05
Group 3 - Stage, window jacks & structural steel over 75 ft.	9.35	.40	.30		.05
Group 4 - Sandblasting, spray	9.45	.40	.30		.05
Add:					
Painters:					
Zone 6 - Painters, tape & float, vinyl & paperhangers & decorators	9.20	.40	.30		.05

MODIFICATIONS P. 11

DECISION NO. OR78-5104 - Mod. #2
(43 FR 28723 - June 30, 1978)
Statewide Oregon

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CHANGE:					
BRICKLAYERS, STONEMASONS:					
Clackamas, Clatsop, Columbia, Gilliam, Hood River, Marion, Multnomah, Morrow, Polk, Sherman, Tillamook, Wasco, (N. of Maupin), Washington, Yamhill, Baker, Union, Umatilla, Wallowa, and N½ Malheur County	$12.94	.85	.85		.15
Benton, Crook Coos, Curry, Deschutes, Douglas, Grant, Harney, Jackson, Jefferson, Josephine, Klamath, Lake, Lane, Lincoln, Linn, Wheeler, Wasco (City of Maupin and south thereof), S½ Malheur	12.75	.75	.75		.08
ELECTRICIANS:					
Baker, Gilliam, Grant, Morrow, Umatilla, Wheeler Counties					
Electricians	13.62	.73	3% + 1.00		.02
Lead Cable Splicers	14.30	.73	3% + 1.00		.02
Coos, Curry, Lincoln, and western portions of Douglas and Lane Counties					
Electricians	13.30	.90	3% + 2.00		.04
Cable Splicers	14.63	.90	3% + 2.00		.04
Harney, Jackson, Josephine, Klamath, Lake, eastern portion of Douglas, Counties					
Electricians	14.13	.90	3% + 1.00		.08
Cable Splicers	15.54	.90	3% + 1.00		.08
ELEVATOR CONSTRUCTORS	13.405	.895	.56	a	.025
GLAZIERS	11.41	.61	.65		.01
MARBLE SETTERS:					
Clackamas, Clatsop, Columbia, Gilliam, Hood River, Multnomah, Morrow, Sherman, Tillamook, Wasco (N½), Washington, and N½ Yamhill Counties	12.94	.85	.85		.15

MODIFICATIONS P. 12

DECISION NO. OR78-5104 - Cont'd

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MASON TENDERS:	$10.08	.95	1.05		.10
PAINTERS:					
Remaining Counties					
Brush	10.82	.55	.70		.10
Spray	11.22	.55	.70		.10
Bridges, high work over 50' (brush)	11.57	.55	.70		.10
Bridges, high work over 50' (spray)	11.97	.55	.70		.10
Drywall tapers	11.42	.65	.60	.50	.06
PLUMBERS:					
Baker, Harney (escept NW), and Malheur Counties	12.32	.79	1.10		.10
Benton (N½), Lincoln, S½ of Tillamook, and Yamhill, Marion and Polk	13.52	1.00	1.65	1.25	.12
Coos, Curry, W. part of Douglas, City of Florence in Lane Co.	13.33	.81	1.40		.10
ROOFERS:					
Baker, Clackamas, Clatsop, Columbia, Gilliam, Grant, Hood River, Morrow, Multnomah, Sherman, Tillamook, Umatilla, Union, Washington, and Wheeler					
Roofers	11.05	.70	1.00		
Handling irritating materials, coal tar or epoxy	11.30	.70	1.00		
Handling irritating materials coal tar or epoxy in confined area	11.55	.70	1.00		
Coos, Crook, Curry, Deschutes, Douglas, Harney, Jackson, Josephine, Klamath, Lake and Lane Counties					
Roofers	11.10	.75	.10		
Spray or application of irritating materials in confined area	12.10	.75	.10		
Wallowa County	10.39	.60	.75		.02
SHEET METAL WORKERS:					
Coos, Curry, Douglas, Klamath, Lake, Lane, Jackson, Josephine	13.085	.71	.61		.045

DECISION NO. OR78-5104 - Cont'd

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
SOFT FLOOR LAYERS:					
Malheur County	$7.76	.49	.10		.10
TILE SETTERS:					
Baker, Clatsop, Clackamas, Columbia, Gilliam, Hood River, Morrow, Multnomah, Sherman, Umatilla, Union, Wallowa, Wasco (N. of Maupin), N½ of Malheur, Tillamook, Washington, N½ Yamhill Counties	11.83	.80	.75		.15
Benton, Coos, Crook, Curry, Deschutes, Douglas, Grant, Harney, Jackson, Josephine, Klamath, Lake, Lane, Lincoln, Linn, Wheeler, Wasco (inc. city of Maupin), S½ Malheur Counties	11.20	.70	.70		.10

FOOTNOTE:

a. Employer credits 8% basic hourly rate of employee with 5 years service; 6% basic hourly rate for 6 months to 5 years service to vacation plan. Six paid holidays. A through F

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
DECISION #TX78-4078 - Mod. #3 (43 FR 35881 - August 11, 1978) Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Cos., Texas					
Change:					
Ironworkers - Zone 1	$ 9.55	.55	1.00		.07
DECISION #TX78-4079 - Mod. #2 (43 FR 35884 - August 11, 1978) Bee, Kleberg & Nueces Cos., Texas					
Change:					
Marble, tile & terrazzo workers	8.43				.02
DECISION #TX78-4080 - Mod. #3 (43 FR 35886 - August 4, 1978) Jefferson & Orange Cos., Texas					
Change:					
Bricklayers & stonemasons	12.46	.63	.60		.04
DECISION #TX78-4088 - Mod. #1 (43 FR 38237 - August 25, 1978) Wichita County, Texas					
Change:					
Plumbers & pipefitters:					
Zone 1 - within 25 miles of Wichita Falls City limits	10.30	.45	.65		.02
Zone 2 - over 25 miles from Wichita Falls City limits	10.80	.45	.65		.02
Zone 3 - over 40 miles from Wichita Falls City limits	11.10	.45	.65		.02
Zone 4 - over 55 miles from Wichita Falls City limits	11.40	.45	.65		.02
Zone 5 - over 70 miles from Wichita Falls City limits	11.70	.45	.65		.02

DECISION NO. WA78-5105 - Mod. #2
(43 FR 28734 - June 30, 1978)
Statewide Washington

CHANGE:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Chelan, Clallam, Douglas, Grays Harbor, Island, Jefferson, King, Kitsap, Kittitas, Lewis, Mason, Okanogan, Pacific(N½), Pierce, San Juan, Skagit, Snohomish, Thurston, Whatcom and Yakima	$14.27	.62	1.30		.06
Remaining Counties	13.54	.62	1.30		.04
BRICKLAYERS:					
Clallam, Island, Jefferson, King, Kitsap, Snohomish, S½ Skagit,	12.41	.80	1.15		.11
Clark, Cowlitz, S½ Pacific, Skamania, Wahkiakum, Klickitat	12.94	.85	.85		.15
Grays Harbor, Lewis, Mason, N½ of Pacific, Pierce, Thurston	12.37	.80	1.20		.06
San Juan, Skagit, Whatcom	12.82	.80	.85		
CEMENT MASONS:					
Clallam, Grays Harbor, Jefferson, King, Kitsap, Kittitas (W. part) Lewis, Mason, Pacific (N½), and Thurston Counties					
Cement Masons	11.53	.70	1.00	.50	.02
Composition, color, mastic, trowel machine, grinder, power tool, gunnite nozzleman	11.78	.70	1.00	.50	.02
ELECTRICIANS:					
Adams, Ferry, Lincoln, Pend Oreille, Spokane, Stevens, and Whitman Counties					
Electricians	14.12	.83	3% + .40		.02
Cable Splicers	14.52	.83	3% + .40		.02
Asotin, Benton, Columbia, Franklin, Garfield, Kittitas, Walla Walla, and Yakima, Cos.					
Electricians	13.52	.83	3% +1.00		.02
Cable Splicers	14.27	.83	3% +1.00		.02

DECISION NO. WA78-5105

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS - Cont'd					
Chelan, Douglas, Grant, and Okanogan Counties					
Electricians	$13.42	.83	3% + 1.00		.02
Cable Splicers	14.76	.83	3% + 1.00		.02
ELEVATOR CONSTRUCTORS:					
Chelan, Clallam, Grays Harbor, Island, Jefferson, King, Kitsap, Kittitas, Lewis, Mason, Pacific (N½), Pierce, San Juan, Skagit, Snohomish, Thurston, Whatcom, and Yakima Counties	14.41	.895	.69	a	.02
Clark, Cowlitz, Klickitat, Pacific(S½), Skamania, and Wahkiakum Counties	13.405	.895	.56	a	.025
GLAZIERS:					
Adams(S.E. part), Benton, Columbia, Franklin, and Walla Walla Counties	10.77	.40	.55	.66	
Asotin, Garfield, and Whitman	10.33	.40	.55	b	
Clallam, Island, Jefferson, Grays Harbor, Kitsap, Lewis, Mason, Pacific (N.½), Pierce, San Juan, Skagit, Snohomish, Thurston, and Whatcom Counties	11.19	.34	.85	b	
Yakima and Kittitas Counties	10.11	.35	.70		.02
Clark, Cowlitz, Klickitat, S.½ Pacific, Skamania, Wahkiakum	11.41	.61	.65		.01
LATHERS:					
Clallam, Island, Jefferson, King, Kitsap, Lewis, Pacific (N.½), Pierce, San Juan, Skagit, Snohomish, and Whatcom Counties	11.82	.70	1.00		.04
MARBLE SETTERS:					
Clallam, Island, Jefferson, King, Kitsap, Snohomish, Skagit (S.½)	12.41	.80	1.15		.11
Grays Harbor, Lewis, Mason, N.½ Pacific, Pierce, and Thurston	12.37	.80	1.20		.06
San Juan, Skagit (N ½), Whatcom	12.82	.80	.85		

DECISION NO. WA78-5105

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MASON TENDERS:					
Clark, Cowlitz, Klickitat, S½ Pacific, Skamania, Wahkiakum	$10.03	.95	1.10		.10
PAINTERS:					
Clark, Cowlitz, Klickitat, S.½ Pacific, Skamania, Wahkiakum					
Brush	10.82	.55	.70	.50	.10
Spray	11.22	.55	.70	.50	.10
Bridges, high work over 50' (brush)	11.57	.55	.70	.50	.10
Bridges, high work over 50' (spray)	11.97	.55	.70	.50	.10
PLASTERERS:					
Clallam, Grays Harbor, Island, Jefferson, King, Kitsap, Lewis, Mason, N.½ Pacific, Pierce, San Juan, Skagit, Snohomish, Thurston, and Whatcom Counties	11.72	.70	1.10		.08
PLUMBERS:					
Clark and Skamania (South part)	14.32	1.50	1.60		.13
ROOFERS:					
Adams, Asotin, Chelan, Douglas, Ferry, Garfield, Grant, Lincoln, Okanogan, Pend Oreille, Spokane, Stevens and Whitman Counties	10.39	.65	1.00		.02
Benton, Franklin, Kittitas, Klickitat, and Yakima Counties					
Roofers, kettlemen, waterproffers, shinglers, spraying	11.59	.60	.30		
Island, San Juan, Skagit, and Whatcom Counties					
Roofers and Waterproofers	9.82	.55	.40		
Slate and tile	10.32	.55	.40		
Clark and Skamania Counties					
Roofers	11.05	.70	1.00		
Handling irritating materials (coal, tar, epoxy)	11.30	.70	1.00		
Handling irritating materials (coal, tar, epoxy) in confined area	11.55	.70	1.00		

DECISION NO. WA78-5105

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
SHEET METAL WORKERS:					
Adams (N.E. part), Ferry, Lincoln (E.½), Pend Oreille, Spokane, and Stevens Counties	10.52	.40	.60		
Adams (S.E. Part), Benton, Columbia, Franklin, Walla Walla	10.04	.40	.80	1.21	
Adams (S.W. part), Chelan, Douglas, Grant, Lincoln(W½), and Okanogan Counties	11.00	.40	.90	.60	
King and Snohomish Counties	11.14	.63	1.00		.05
SPRINKLER FITTERS:					
Skagit, Snohomish, King, Island, Kitsap, Pierce, and Thurston	15.31	75	1.55		.11
TERRAZZO WORKERS:					
Adams(except city of Othello), Asotin, Columbia, Ferry, Garfield, Linclon, Pend Oreille, Spokane, Stevens, Whitman, and Okanogan (Grand Coulee area)	11.60	.65	.70		
Clallam, Island, Jefferson, King, Kitsap, Skagit(Southern part), and Snohomish Counties	12.12	.80	1.00		.05
San Juan, Skagit(N.part), and Whatcom Counties	12.82	.80	.85		
Grays Harbor, Lewis, Mason, Pierce, and Thurston Counties	12.37	.80	1.20		.06
TILE SETTERS:					
Adams(except City of Othello), Asotin, Columbia, Ferry, Garfield, Lincoln, Pend Oreille, Spokane, Stevens, Whitman, and Okanogan (Grand Coulee area)	11.60	65	70		
Clallam, Island, Jefferson, King, Kitsap, Skagit(S.part), and Snohomish Counties	12.12	.80	1.00		.05
Grays Harbor, Lewis, Mason, Pierce, and Thurston Counties	12.37	.80	1.20		.06
San Juan, Skagit(N½), Whatcom	12.82	.80	.85		

MODIFICATIONS P. 19

DECISION NO. WA78-5105

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS (DREDGING)					
AREA 1:					
Group 1	$12.02	.85	1.00		.11
Group 2	12.12	.85	1.00		.11
Group 3	12.46	.85	1.00		.11
Group 4	12.51	.85	1.00		.11
Group 5	12.56	.85	1.00		11
Group 6	12 88	85	1.00		.11
Group 7					
(a)	13 27	.85	1.00		.11
(b)	13 82	85	1 00		.11
AREA 2:					
Group 1	12.02	.85	1.00		.11
Group 2	12.12	.85	1.00		.11
Group 3	12.46	.85	1.00		.11
Group 4	12.51	.85	1.00		.11
Group 5	12.56	.85	1.00		.11
Group 6	12.88	.85	1.00		.11
Group 7					
(a)	13.27	.85	1.00		.11
(b)	13.82	.85	1.00		.11

SUPERSEDEAS DECISION

STATE: Florida
DECISION NUMBER: FL78-1084
COUNTIES: See below*
DATE: Date of Publication
Supersedes Decision No. FL75-1104 dated October 24, 1975 in 40 FR 49949
DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

*Citrus, Hernando, Hillsborough, Pasco, Pinellas, & Sumter

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Air Conditioning/ Heating Mechanic	5.00			.10	
Bricklayers	7.00				
Carpenters	6.00				
Cement Masons	4.00				
Electricians	6.10	7%	3%	5%	.05
Insulation Installer	3.81				
Glaziers	7.15	.25			.01
Ironworkers	5.08				
Laborers	3.00				
Mason Tender	4.00				
Lather	7.09		.20		.01
Painters	5.00				
Plasterers	7.10				
Plumbers and Pipefitters	5.89				
Roofers	5.46				
Sheet Metal Workers	4.91				
Tile Setters	7.00				
Truck Drivers	3.25				
Power Equipment Operators					
Backhoe	5.17				
Bulldozer	5.50				
Compactor/Roller	4.68				
Crane, Derrick, Dragline	5.42				
Front End Loader	4.75				
Grader	5.13				

STATE: Michigan COUNTIES: See Below
DECISION NO. MI78-2072 DATE: Date of Publication
Supersedes Decision No. MI78-2010, dated March 10, 1978 in 43 FR 10193
DESCRIPTION OF WORK: Building (Does not include single family homes and garden type apartments up to and including 4 stories) and Heavy (excluding Bridge Airport and Sewer) Construction.

COUNTIES: Alcona, Alpena, Charlevoix, Emmet, Grand Traverse, Leelanau, Mason, Montmorency, Muskegon, Oceana, Oscoda and Presque Isle.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.85	.84	1.63		.02
BOILERMAKERS	11.955	1.10	1.20	2.00	.03
BRICKLAYERS:					
Mason County:					
Bricklayers; Stonemasons; Marble-Tile Workers, Cement Masons & Plasterers	8.70	.65	.25		
Muskegon & Oceana Counties					
Bricklayers & Stonemasons	9.195	.55	.75		
Marble Masons	8.75	.55	.70		
Terrazzo & Tile Workers	8.50	.55	.70		
Plasterers	10.68	.60	.50		.02
Remaining Counties					
Bricklayers; Stonemasons; Plasterers-Marble Workers	9.93	.70	.25		.02
Terrazzo & Tile Workers	9.37	.70	.25		
CARPENTERS:					
Mason, Muskegon & Oceana Counties					
Carpenters	10.50	.60	.70		.04
Millwrights	12.25	.60	.70		.05
Piledrivers	10.90	.60	.70		.04
Remaining Counties					
Carpenters & Soft Floor Layers	9.31	.60	.70		.03
Millwrights	9.81	.60	.70		.03
Piledrivers	9.76	.60	.70		.03
CEMENT MASONS:					
Muskegon & Oceana Counties	8.05	.50	.50		.02
Remaining Counties	9.48	.70	.25		.02
ELECTRICIANS:					
Charlevoix, Grand Traverse, Leelanau & Emmet (except Wawatan Township) Counties and (Grant, Freesoil, and Meade Townships) in Mason County	11.50	.50	3%+.40		.1 of 1%
Muskegon, Oceana and the Remainder of Mason Counties	$11.68	.50	3%+.35		.03
Remaining Counties & (Wawatan Township) in Emmet County:					
Electricial Contractors $35,000 and below	9.75	.50	3%+.30		.1 of 1%
Electrical Contracts in excess of $35,000	11.70	.50	3%+.30		.1 of 1%
ELEVATOR CONSTRUCTORS:					
Alcona, Alpena, Montmorency, Oscoda and Presque Isle:					
Elevator Constructor	11.21	.745	.56	a	.025
Elevator Constructor Helpers	70%JR	.745	.56	a	.025
Elevator Constructor Helpers (Prob.)	50%JR				
ELEVATOR CONSTRUCTORS:					
Remaninder of Counties:					
Elevator Constructors	10.195	.745	.56	a	.025
Elevator Constructors Helpers	70%JR	.745	.56	a	.025
Elevator Constructors Helpers (Prob.)	50%JR				
GLAZIERS:					
Emmet & Muskegon Counties	$ 8.55	.40	.30		
Charlecoix, Grand Traverse, Leelanau, Mason, & Oceana Counties	8.30	.40	.30		
IRONWORKERS:					
Alcona, Alpena, Montmorency, Oscoda and Preque Isle Counties:					
Structural and Ornamental	11.18	8%	14%	17%	.09
Reinforcing	10.10	.98+.25	15%	15%	.07
Fence Erectors	10.18	8%	14%	17%	.09
Remaining Counties	11.26	6%	8%		.03
LATHERS:	8.85	.64	.10	.50	.01
Grand Traverse County	9.60	.92	.30		.01
Muskegon County	9.82	.92	.30		.01
PAINTERS:					
Alcona and Oscoda Counties					
Brush	8.85	.50	.80		.02
Spray	9.70	.50	.80		.02

DECISION NO. MI78-2072

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Grand Traverse and Leelanau Counties and that portion of Charlevoix County lying South of and straight line drawn from Charlevoix (city) to Elmira					
Brush	$ 8.45	.50			.02
Spray; Tapers	9.10	.50			.02
Mason County	8.25				
Muskegon & Oceana Counties					
Brush, Tapers	8.00				
Paper hangers	8.25				
Spray & Sandblast	8.50				
Remainder of Charlevoix County and Remaining Counties					
Brush & Drywall	9.15				
Spray	9.90				
PLUMBERS & STEAMFITTERS:					
Alcona and Oscoda Counties	11.34	.85	.60	1.80	
Alpena, Montmorency & Presque Isle Counties	12.05	.35	.60		
Mason, Muskegon & Oceana Counties	10.71	1.19	.75		.04
Remaining Counties	11.41	.60	.50		.06
ROOFERS:					
Mason, Muskegon & Oceana Counties	9.05	.67		.20	
Remainder of Counties:					
Composition, Damp & Waterproofers	9.60				
SHEET METAL WORKERS:					
Charlevoix, Emmet, Grand Traverse and Leelanau Counties	10.70	.50	.53		.05
Mason, Muskegon & Oceana Counties	10.40	.77	.65	.67	.02
Remaining Counties	11.11	.65	1.00		.03
SPRINKLER FITTERS	12.10	.75	1.05		.03

DECISION NO. MI78-2072

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS:					
Alcona, Alpena, Montmorency, Oscoda & Oreque Isle Counties					
Regular Truck Driver	$ 7.87	b26.00	b31.00	.38	
8 cu. yds. and over	7.97	b26.00	b31.00	.38	
Euclid Type Bottom & End Dump	8.17	b26.00	b31.00	.38	
Charlevoix, Emmet, Grand Traverse and Leelanau Counties					
Regular Truck Driver	7.95	b26.00	b31.00	c	
8 cu. yds, and over	8.05	b26.00	b31.00	c	

Welder receive rate prescribed for craft to which welding is incidental.

FOOTNOTES:

a. Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years; 6% contribution for more than 5 years-plus 7 Paid Holidays-New Years Day-Memorial Day-Independence Day-Labor Day-Thanksgiving Day-Day after Thanksgiving & Christmas Day

b. Per week; Per Employee & Dental & Optical

c. Paid vacation computed at a 40 hour week at straight time as follows: one year or more - one week; three years or more - two weeks; eight years or more - three weeks; and 7 Paid Holidays provided employee has been in service of employer 20 days or more and worked the full scheduled day prior to and after the holiday - New Years Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day and the Friday after Christmas Day.

DECISION NO. MI78-2072

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS:					
Mason County					
Group 1	$ 7.30	.65	.35		.04
Group 2	7.45	.65	.35		.04
Group 3	7.75	.65	.35		.04
Group 4	7.65	.65	.35		.04
Group 5	7.70	.65	.35		.04
Group 6	7.75	.65	.35		.04
Muskegon and Oceana Counties					
Group 1	7.21	.65	.35	.55	.04
Group 2	7.36	.65	.35	.55	.04
Group 3	7.46	.65	.35	.55	.04
Group 4	7.71	.65	.35	.55	.04
Remaining Counties					
Group 1	6.80	.65	.35	.40	.04
Group 2	6.95	.65	.35	.40	.04
Group 3	7.40	.65	.35	.40	.04

LABORERS:

Mason County

Group 1 - Building and Heavy Construction Laborers
Group 2 - Plaster and Mason Tenders; Mortar Mixers; Material Mixers; All power Tools; Vibrator; Chain saw; Nozzleman; Green Cut Concrete work
Group 3 - Jackhammer; Acetylene Torch; Windlass and Tugger Operators; swing Scaffold Chimneys; Tower, Crane Scaffold; Rock Crusher
Group 4 - Pipelayers or Crock Layers in Buildings
Group 5 - Plasterers Tenders - Machine pumped
Group 6 - Work on Scaffold 30' in height or more

Muskegon and Oceana Counties

Group 1 - All Construction Laborers on Building and Heavy Construction Pumps and well Wheels
Group 2 - Plasterer tender; Material Mixers; Operators of Portable Mixers; Air, Electric or Gasoline Tools; Mortar Driver Buggies; Swing Scaffold
Group 3 - Jackhammer Operator, Crocklayers & Caisson workers in Buildings
Group 4 - Top men on Chimney or Towers over 30' in Height

Remaining Counties:

Group 1 - Building and Heavy Construction Laborers
Group 2 - Mortar Mixer; Material Mixers (hand or machine); Vibrator Operators; Operators of Concrete Mixers; Chipping Hammer; Concrete Breakers (90 lb. hammer or less); Tamping Machine (air, gas or electric); Sand blasters; Operator or Motor Driven Buggies; Plaster Mixer; Plasterers Tenders
Group 3 - Cement Gun Nozzleman

DECISION NO. MI78-2072

LC - ZONE II

LINE CONSTRUCTION: ZONE 11	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen; Heavy Equipment Operator	$11.00	.45	3%	a	.5%
Cable Splicer	11.44	.45	3%	a	.5%
Combination Digger Operator; Tractor Operator Groundman					
1st 6 months	7.94	.45	3%	a	.5%
Over 6 months	8.58	.45	3%	a	.5%
Light Equipment Operator - Groundman; Distribution Line					
1st 6 months	6.90	.45	3%	a	.5%
Over 6 months	7.53	.45	3%	a	.5%
Combination Truck Driver Groundman	6.08	.45	3%	a	.5%

FOOTNOTES:

7 paid Holidays; New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Day after Thanksgiving Day; and Christmas Day.

DECISION NO. MN78-2072

MICH-3-PEO-1-2

POWER EQUIPMENT OPERATORS:
BUILDING & HEAVY CONSTRUCTION

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$12.75	.90	1.25		.05
CLASS B	12.50	.90	1.25		.05
CLASS C	12.00	.90	1.25		.05
CLASS D	11.20	.90	1.25		.05
CLASS E	11.00	.90	1.25		.05
CLASS F	9.80	.90	1.25		.05
CLASS G	9.10	.90	1.25		

CLASS A - Crane with main boom & jib 220' or longer

CLASS B - Crane with main boom & jib 140' or longer, tower cranes, gantry cranes, whirley derrick

CLASS C - Regular equipment operator, cranes, stiff leg derrick, scraper, dozer, grader, front end loader, hoist, job mechanic & head grease man

CLASS D - Air Tugger (single drum), Material Hoist, Boiler Oprs., Sweeping Machine, winch Truck, Bob Cat & Similar type equipment, Fork Truck (over 20' lift)

CLASS E - Pump 6" or over, Well Points, Freeze systems, Boom truck (non Swinging) Fork Truck (20' Lift)

CLASS F - Air Compressor, Welder, Generators, Pumps under 6", Grease Man, Conveyors

CLASS G - Oiler, Firemen & Heater Operator

DECISION NO. MN78-2072

MICH-2-PEO-SE

POWER EQUIPMENT OPERATORS:
STEEL ERECTION

ALCONA, ALPENA, MONTMORENCY, OSCODA & PRESQUE ISLE COUNTIES

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$11.57	.55	.75	10%	.05
CLASS B	11.33	.55	.75	10%	.05
CLASS C	10.85	.55	.75	10%	.05
CLASS D	10.70	.55	.75	10%	.05
CLASS E	9.61	.55	.75	10%	.05
CLASS F	8.65	.55	.75	10%	

CLASS A - Engineer when operation combination of boom jib 220' or longer
CLASS B - Engineer when operating combination of boom & jib 140' or longer Tower crane & derrick operator (where opeators work stations is 501 Or more above first sub l[illegible]
CLASS C - Crane operato[illegible]b mechanic
CLASS D Hoisting operat[illegible]
CLASS E Compressor (or [illegible]er) operator
CLASS F - Oiler or fireman

MICH-6-PEO-SE

POWER EQUIPMENT OPERATORS:
STEEL ERECTION

REMAINING COUNTIES

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$13.10	.90	1.25		.05
CLASS B	12.85	.90	1.25		.05
CLASS C	12.35	.90	1.25		.05
CLASS D	11.55	.90	1.25		.05
CLASS E	10.30	.90	1.25		.05
CLASS F	9.10	.90	1.25		

CLASS A - Crane operator w/main boom & jib 220' or longer
CLASS B - Crane operator w/main boom & jib 140' or longer; power cranes, gantry crane; whirley derrick
CLASS C - Regular equipment operator; crane; dozer; loader; hoist, straddle wagon, Job mechanic
CLASS D - Air tugger (single drum); material hoist, pump 6' or over
CLASS E - Air compressor, welder, generators-conveyors
CLASS F - Oiler & Fireman

DECISION NO. MI78-2072

MICH-9-PEO-U-Z-2

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION

	Basic Hourly Rates	Fringe Benefits Payments			
		H.& W	Pensions	Vocation	Education and/or Appr. Tr.
CLASS I	$ 9.24	.80	1.00	10%	.05
CLASS II	8.98	.80	1.00	10%	.05
CLASS III	8.52	.80	1.00	10%	.05
CLASS IV	8.27	.80	1.00	10%	.05

CLASS I - Power shovel, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip fom paver slope paver, conveyor loader (euclid type)

CLASS II - Trencher (6' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer (less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharge or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist, boom truck (power sing type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM), air compressors 600 cu. ft. per min. or larger), pumpcrete machine (and similar equipment), mechanic helper, maintenance man, boom truck(non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ dy or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propelled or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 or more up to 4" discharge if used 3 hours or more a day gas or diesel powered - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachments), finishing machine (concrete), roller (other than asphalt), cutter machine (self-propelled), concrete saw (40 H.P. or over)

SUPERSEDEAS DECISION

STATE: Michigan — COUNTIES: See Below
DECISION NO.: MI78-2073 — DATE: Date of Publication
Supersedes Decision No. MI78-2011, dated March 10, 1978 in 43 FR 10198
DESCRIPTION OF WORK: Building (Does not include single family homes and garden type apartments up to and including four stories) and Heavy (excluding Bridge, Airport and Sewer) Construction.

COUNTIES: Alger, Baraga, Chippewa, Dickinson, Gogebic Houghton, Keweenaw, Mackinac, Marquette & Ontonagon

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vocation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Chippewa & Mackinac Counties	$11.85	.95	1.63		.02
Gogebic & Ontonagon Counties	11.10	.40	.50		
Remainder of Counties	10.81	.70	.50	.65	.05
BOILERMAKERS	11.955	1.18	1.20	2.00	.03
BRICKLAYERS:					
Alger & Marquette Counties:					
Bricklayers, Stonemarons, Plasterers, & Marble-Tile-Terrazzo Workers	9.62	.75	.50		.01
Chippewa & Mackinac Counties:					
Bricklayers & Stonemasons	9.59	.70	.60		
Plasterers	9.44	.70	.60		
Tile & Terrazzo Workers	9.39	.70	.60		
Remainder of Counties:					
Bricklayers, Stonemasons, Plasterers, Marble-Tile and Terrazzo Workers	9.62	.75	.50		.01
CARPENTERS:					
Carpenters & Soft Floor Layers	10.04	.60	.70		.02
Millwrights	11.19	.60	.70		.02
Piledrivermen	9.44	.60	.60		.01
CEMENT MASONS:					
Alger & Marquette Counties	9.12	.75	.50		.01
Chippewa & Mackinac Counties	9.02	.70	.60		
Remainder of Counties	9.12	.75	.50		.01
ELECTRICIANS:					
Dickinson County:					
Contracts $50,000 or more & all Industrial work	11.06	.40	3%		.5%
Contracts Less than $50,000	9.74	.40	3%		.5%
Alger & Marquette Counties:					
Contracts over $50,000	12.05	.45	3%+.45		½ of 1%
Contracts $50,000 or less	10.56	.45	3%+.45		½ of 1%

DECISION NO. MI78-2073

ELECTRICIANS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Chippewa & Mackinac Counties	$11.30	.50	3%		15.00 ply
Gogebic County	10.80	4%	3%	11%	3%
Remainder of Counties:					
Contracts $45,000 & over	11.54	.50	3%		½ of 1%
Contracts up to $45,000	8.75	.0	3%		½ of 1%
ELEVATOR CONSTRUCTORS:					
Constructors	10.765	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (Prob.)	50%JR				
IRONWORKERS	10.00	.70	1.00	1.70	.04
PAINTERS:					
Dickinson County:					
Commercial & Industrial	8.95		.75		
Alger & Marquette Counties					
Brush	9.75				
Glaziers	9.75				
Bridges, Water Tanks, Radio & TV	12.00				
Chippewa & Mackinac Counties:					
Commercial-Industrial & Sign Painter	8.10			1.50	
Taper-Hand	8.60			1.50	
Steel	10.60			1.50	
Glaziers	6.90			1.50	
Baraga, Houghton, Keweenaw & the northern portion of Ontonagon County:					
Brush, Paperhangers, Tapers and Glaziers	8.00				
Spray & Sandblasting	8.50				
Gogebic County & the Remainder of Ontonagon County:					
Brush, Paperhangers	6.00				
Spray	6.00				
	6.50				

DECISION NO. MI78-2073

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PLUMBERS & STEAM FITTERS	$ 9.43	.70	.70	1.00	.02
ROOFERS	9.15		.50		
SHEET METAL WORKERS	9.86	.70+.10	.65	1.25	.05
SPRINKLER FITTERS	12.10	.75	1.05		.08
TRUCK DRIVERS:					
Truck Driver	7.72	b22.00	b16.00		
Heavy Duty, Double Axle & Semi	7.85	b22.00	b16.00		
Euclid	8.08	b22.00	b16.00		

FOOTNOTES:

a. 7 Paid Holidays-New Year's Day-Memorial Day- Independence Day-Labor Day-Thankdgiving Day-Day after Thanksgiving & Christmas Day plus employer contributes 8% of Regular Hourly Tate to vacation pay credit for employee who has worked in business more than 5 years & 6% for employees in business less than 5 years

b. Per Week; Per Employee

DECISION NO. MI78-2073

Welders receive rate prescribed for craft performing operation to which welding is incidental.

FOOTNOTES:

a. Employer contributes 2% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years; 4% contribution for more than 5 years.

b. Per Week; Per Employee

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Class A	$ 8.00	.65	.35		.04
Class B	8.10	.65	.35		.04
Class C	8.40	.65	.35		.04
Class D	8.55	.65	.35		.04

LABORERS

CLASS A: General Construction Laborers

CLASS B: Chipping Hammers; Concrete Mixers; Green Cutting (air, electric or gas); Material Mixers (hand or machine; Motor driven buggies; Mortar Mixers; Sand Blasters; Tamping Machines; Vibrator operator; Laborers with concrete mixer to pour, including pour from trucks

CLASS C: Blasters; Buster Operators; Cement Gun Nozzleman; Drillers; Layers of all non-metallic pipe; Mixers

CLASS D: Underground Work, Tunnels and Shafts - muckers, caisson workers, miners, drillers, blasters.

DECISION NO. MI78-2073

LC -ZONE II

LINE CONSTRUCTION: ZONE 11	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen; Heavy Equipment Operator	$11.00	.45	3%	a	.5%
Cable Splicer	11.44	.45	3%	a	.5%
Combination Digger Operator; Tractor Operator Groundman'					
1st 6 months	7.94	.45	3%	a	.5%
Over 6 months	8.58	.45	3%a	a	.5%
Light Equipment Operator Groundman; Distribution Line Truck Driver Operator:					
1st 6 months	6.90	.45	3%	a	.5%
Over 6 months	7.53	.45	3%	a	.5%
Combination Winch Truck Driver Groundman:					
1st 6 months	6.28	.45	3%	a	.5%
Over 6 months	7.18	.45	3%	a	.5%
Combination Truck Driver Groundman	6.08	.45	3%	a	.5%

FOOTNOTE:

a. 7 paid Holiday: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Day after Thanksgiving Day; and Christmas Day.

DECISION NO. MI78-2073 MICH-7-PEO-1-2-SE-U

POWER EQUIPMENT OPERATORS: BUILDING, HEAVY & UNDERGROUND CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$ 9.23	.90	1.25	11%	.02
CLASS B	8.37	.90	1.25	11%	.02
CLASS C	7.85	.90	1.25	11%	.02
CLASS D	7.29	.90	1.25	11%	

ASS A - Regular equipment operator, crane, dozer, front end loader, ob mechanic
ASS B - Air Track drill, boom truck, concrete mixers, fork truck, aterial hoist & tugger, pumps 6" or over, pumpcrete, belt crete, eeze crete, sweeping machine trencher, winches, well pointsa nd reeze systems
ASS C - Air compressor, conveyor, concrete saw, farm tractor (without ttachments) generatOR, guard post driver, mulching pumps under 6" elders
ASS D - Oiler, fireman, heater operator

POWER EQUIPMENT OPERATORS: STEEL ERECTION					
CLASS 1 - Operator	$ 8.95	.80	1.00	10%	.02
CLASS 2 - Compressor o& Welder	7.95	.80	1.00	10%	.02
CLASS 3 - Oiler & Fireman	7.05	.80	1.00	10%	

SUPERSEDEAS DECISION

STATE: Michigan COUNTY: Marquette
DECISION NO.: MI78-2074 DATE: Date of Publication
Supersedes Decision No. MI78-2012, dated March 10, 1978 in 43 FR 10201
DESCRIPTION OF WORK: Residential Construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$10.81	.70	.50		.05
BOILERMAKERS	11.955	1.18	1.20	2.00	.03
BRICKLAYERS & STONEMASONS	9.62	.75	.50		.01
CARPENTERS & SOFT FLOOR LAYERS	7.01	.60	.50		.01
CEMENT MASONS	9.12	.75	.50		.01
ELECTRICIANS	8.20	.45	3%		½of1%
ELEVATOR CONSTRUCTORS:					
Constructors	10.765	.745	.56	a+b	.025
Helpers	70%JR	.745	.56	a+b	.025
Helpers (Prob.)	50%JR				
IRONWORKERS	10.00	.70	1.00	1.70	.04
LABORERS:					
Laborers	8.00	.65	.35		.04
Chipping Hammers; Concrete Mixers, Green Cutter (Air, Electric or Gas), Material Mixers, Mortar Mixers, Mortor driven buggy operator, sand-blasters, Tamping machines, vibrator operators	8.10	.65	.35		.04
MILLWRIGHTS	11.19	.60	.60		.02
PAINTERS:					
Brush & Glaziers	9.25				
PLASTERERS	9.62	.75	.50		.01
PLUMBERS & STEAMFITTERS	9.43	.70	.70	1.00	.02
ROOFERS	9.15		.50		
SHEET METAL WORKERS	9.96	.70+.10	.65		.05
SPRINKLER FITTERS	12.10	.75	1.05		.08
TILE-MARBLE & TERRAZZO WORKERS	9.62	.75	.50		.01
TRUCK DRIVERS:					
Regular	7.72	22.00c	16.00c		
Heavy Duty, double axle and semi	7.85	22.00c	16.00c		
Euclid type equipment	8.08	22.00c	16.00c		

DECISION NO. MI78-2074

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Power Equipment Operators					
Regular Equipment Operator Crane, Dozer, Front End Loaders Job Mechanic	$ 9.23	.90	1.25	11%	.02
Air Track Drill, Boom Truck Concrete Mixers, Fork Truck, Material Hoist and Tugger, Pump, 6" andover, Pumpcrete, Belt Crete, Squeeze crete, Sweeping Machine, trencher, Winches, Well points and Freeze Systems	8.37	.90	1.25	11%	.02
Welders - receive rate prescribed for craft performing operation to which welding is incidental.					

PAID HOLIDAYS: (WHERE APPLICABLE)

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Day after Thanksgiving Day & Christmas Day.

FOOTNOTES:

a. Six paid holidays: A through G

b. Employer contributes 8% of regular hourly rate to vacation credit for employee who has worked in business more than 5 years. Emoployer contributes 6% of regular hourly rate to vacation pay credit for employee who has worked in ousiness less than 5 years.

c. Per week, Per employee

SUPERSEDEAS DECISION

STATE: Michigan COUNTIES: See Below
DECISION NO. MI78-2075 DATE: Date of Publication
Supersedes Decision No: MI78-2013, dated March 10, 1978 in 43 FR 10202
DESCRIPTION OF WORK: Building (Does not include single family homes and garden type apartments up to and including four stories) and Heavy (excluding, Bridge, Airport and Sewer) Construction

COUNTIES: Allegan, Berrien Calhoun, Clinton, Eaton, Ingham, Jackson & Kalamazoo

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Berrien County	$12.98	.65	.90		
Remaining Counties	11.85	.95	1.63		.02
BOILERMAKERS	11.955	1.18	1.20	2.00	.03
BRICKLAYERS & STONEMASONS:					
Allegan County (Casco, Clyde Ganges and Lee Townships) and Berrien County	10.75	.95	.60		
Allegan County (Allegan, Cheshire, Gun Plain, Martin, Otsego, Trowbridge, Valley, and Watson Townships) and Kalamazoo County	10.94	.85	.35		.09
Allegan County (Remainder)	9.10	.55	.25		.04
Calhoun County and Bellevue, Carnel, Kalamo, and Walton Townships in Eaton County	11.45	.55	.35		
Clinton and Ingham (except Onondaga, Leslie, Bunker Hill and Stockbridge Townships) Counties and the remainder of Eaton County	11.53		.90		.01
Jackson County and remainder of Ingham County	11.92	1.10	.80		
CARPENTERS:					
Berrien County (Chickaming, New Buffalo and Three Oaks Townships)	12.78	.65	.67		.05
Clinton, Eaton (except Bellevue, Walton, Kalamo and Vermontville Townships), Ingham & Jackson Counties	10.61	.60	.60		.01
Remaining Counties and the remainder of Berrien and Eaton Counties	10.50	.60	.70		.04

DECISION NO. MI78-2075

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CEMENT MASONS:					
Kalamazoo County; Calhoun Co; Allegan Co., (Twps of Allegan, Cheshire, Gunn Plain, Martin, Otsego, Trowbridge, Valley & Watson)	$10.32	.85	.35		.02
Allegan County (Casco, Ganges & Lee Townships) and Berrien County	9.95	.95	.60		
Remainder of Allegan County	9.32	.50	.50		.02
Remainder of Counties	10.40	.60	.50		.02
ELECTRICIANS:					
Allegan County (Laketon, Fillmore, Leighton Townships	11.03	.50	3%+.35		.01
Allegan County (Remainder) and Kalamazoo County	12.03	.50	9½%		.01
Berrien County	11.85	4.8%	7%		.2%
Calhoun County and Sunfeild, Vermontville, Kalamo, Bellevue Eaton and Brookfield townships in Eaton County	12.15	.50	3%		.01
Clinton and Ingham (except Onondaga, Leslie, Stockbridge and Bunker Hill Townships) Counties and the remainder of Eaton County	12.57	.50	3%+1.00		.5%
Jackson County	11.01	4%+.50	3%+.50		3/4 of 1%
Remainder of Ingham County	11.81	4%+.50	3%+.50		3/4 of 1%
ELEVATOR CONSTRUCTORS:					
Allegan, Kalamazoo, and Calhoun Counties:					
Constructor	10.81	.745	.56	a	.025
Helper	70%JR	.745	.56	a	.025
Helper (Prob.)	50%JR				
Berrien County:					
Constructor	10.83	.745	.56	a	.025
Helper	70%JR	.745	.56	a	.025
Helper (Prob.)	50%JR				.025

DECISION NO. MI78-2075

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELEVATOR CONSTRUCTORS (CONT'D)					
Eaton, Ingham & Jackson Counties:					
Constructor	$12.41	.745	.56	a	.025
Helper	70%JR	.745	.56	a	.025
Helper (Prob.)	50%JR				
IRONWORKERS:					
Berrien County	11.45	.90	1.33		.03
Clinton, Ingham & Jackson Cos.					
Structural & Ornamental	11.18	8%	14%	17%	.09
Fence Drectors	10.18	8%	14%	17%	.09
Reinforcing	10.10	.98+.25	15%	15%	.07
Remaining Counties	11.26	8%			.03
LATHERS:					
Ingham & Jackson Cos.	9.92	.92	.30		.01
Calhoun County	9.82	.92	.30		.01
MARBLE, TILE & TERRAZZO WORKERS					
Allegan Co. (Gun Plain Otsego, Trowbridge Valley, Allegan, Cheshire, Martin and Watson Townships) and Kalamazoo County	9.10	.60			.05
Remainder of Allegan Co.	8.35	.45	.25		
Clinton, Ingham (except Onogdaga, Leslie, Bunker Hill, and Stockbridge Townships) and Eaton (except Kalamo, Carmel, Bellevue, and Walton Townships) Counties	10.83		.80		
Calhoun Co. & Bellevue, Carmel, Kalamo & Walton Twps. in Eaton County		.85	.35		
Marble Setters	11.45	.55	.35		
Tile & Terrazzo Workers	8.85	.85	.35		
Jackson County and the Remainder of Ingham County					
Tile & Terrazzo Workers	11.00	1.10	.80		
Marble Setters	11.92	1.10	.80		
PAINTERS:					
Allegan Co. (Northern portion)					
Brush	8.55	.50	.25		.02
Spray, Sandblasting, & Steamcleaning	9.05	.50	.25		.02

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PAINTERS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Allegan County (S.E.¼) and Kalamazoo County					
Brush; Drywall Taping; Pan Roller	$ 9.45		.30		
Swing Stage; Structural Steel	10.10		.30		
Spray	10.35		.30		
Berrien County					
Brush	9.65				
Structural Steel	10.65				
Calhoun County					
Brush; Roller	8.30	.25			
Clinton, Eaton & Ingham Counties					
Brush and Roller & Tapers	11.39	.50	.40		.0025
Structural Steel	11.79	.50	.40		.0025
Spray & Sandblasting	12.14	.50	.40		.0025
Jackson County					
Brush and Roller	11.02	.63	.20		.02
Spray and Sandblasters	11.77	.63	.20		.02
Drywall Taper	11.42	.63	.20		.02
PLASTERERS:					
Allegan County (Casco, Clyde, Ganges and Lee Townships) and Berrien County	10.15	.95	.60		
Remainder of Allegan County and Remainder Counties	10.68	.60	.50		.03
PLUMBERS:					
Allegan County (Northern Tier Townships)	12.09	.60+.15	.90		.05
Allegan County (Remainder) and Kalamazoo County	11.71	.60	.86		

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PLUMBERS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Berrien County (except city of Niles and vicinity)	$12.17	.94	.65		
City of Niles and Vicinity in Berrien County	11.10	.48	.95		.10
Calhoun County and Bellevue, Olivet, Hastings and Charlotte in Eaton County	11.94	1.30	.73		
Clinton and Ingham Counties and Sunfeild, Roxand, Oneida, Delta and Windson townships in Eaton County	12.16	.25	1.25		
Jackson County	11.20	.87+.30	.80		.02
ROOFERS:					
Jackson County					
Composition	10.50	.85	.50	1.05	.10
Slate & Tile	11.25	.85	.50	1.05	.10
Allegan County					
Built-Up	7.25	.45	.35	.35	
Slate, Tile & Asbestos	7.50	.45	.35	.35	
Calhoun and Kalamazoo Counties:					
Composition	10.35			.25	
Slate, Tile & Asbestos	10.60			.25	
Clinton, Eaton and Ingham Cos.	9.30		.65	.45	
SHEET METAL WORKERS:					
Berrien County	10.98	.65	6.15		.035
Remaining Counties	9.98	.85	1.08	.68	.04
SOFT FLOOR LAYERS:					
Allegan, Berrien (except Chickaming, New Buffalo and Three Oaks townships), Calhoun, Kalamazoo Counties and Bellevue, Vermontville, Kalmo and Walton townships in Eaton County	8.80	.60	.70		.01
Clinton and Ingham Counties and the remainder of Eaton County	9.28	.60	.60		.01
Jackson County	10.61	.60	.60		.01
Chickaming, 3 Oaks & New Buffalo Twps. in Berrien Co.	12.78	.65	.67		.05

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
SPRINKLER FITTERS	$12.37	.75	1.05		.08
TRUCK DRIVERS:					
Allegan, Berrien and Kalamazoo Counties:					
8 cu yds. & under	8.84	b24.00	b22.00		
8 cu yds. & over	9.00	b24.00	b22.00		
Low Boys Semis	9.11	b24.00	b22.00		
Calhoun County					
Less than 8 cu. yds.	7.95	b21.00	b12.00	.20	
8 cu. yds, and over; Semi Tandem	8.05	b21.00	b12.00	.20	
Clinton, Eaton and Ingham Cos.					
8 cu yds. & under	8.11	b26.00	b31.00	c	
Truck Drivers on dump trucks 8 cu. yds. Capacity and over pole trailers	8.21	b26.00	b31.00	c	
Low boys drivers; Double bottom drivers	8.31	b26.00	b31.00	c	
Jackson County	5.95	b24.00	b22.00		
Welders receive rate prescribed for craft performing operation to which welding is incidental.					

DECISION NO. MI78-2075

PAID HOLIDAYS (WHERE APPLICABLE)

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Day after Thanksgiving; G-Christmas Day

FOOTNOTES:

a. Employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business less than 5 years, 6% contribution for more than 5 years, plus 7 paid holidays - A through G

b. Per week, Per employee

c. One year's service, one week vacation; 3 years service, two weeks vacation

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LABORERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Allegan, Berrien, Calhoun and Kalamazoo Counties					
Group 1	$ 8.35	.65	.35	.55	.04
Group 2	8.50	.65	.35	.55	.04
Group 3	8.60	.65	.35	.55	.04
Group 4	8.85	.65	.35	.55	.04
Clinton, Eaton and Ingham Counties					
Group 1	8.75	.65	.35	a	.04
Group 2	8.83	.65	.35	a	.04
Group 3	8.89	.65	.35	a	.04
Group 4	9.04	.65	.35	a	.04
Group 5	8.99	.65	.35	a	.04
Group 6	9.11	.65	.35	a	.04
Group 7	9.365	.65	.35	a	.04
Jackson County					
Group 1	8.23	.55	.35	.80	.04
Group 2	8.73	.55	.35	.80	.04

LABORERS:

Allegan, Berrien, Calhoun and Kalamazoo Counties
Group 1 - All construction laborers on buildings and Heavy Construction Pumps and Well Wheels
Group 2 - Plasterer Tenders, Material Mixers, Operators of Portable Mixers; Air, Electric or Gasoline Tools; Motor Driven Buggies; Swing Scaffolds
Group 3 - Jackhammer Operators, Crocklayers & Caisson Workers in Building
Group 4 - Top men on Chimney or Towers over 30' in height
Clinton, Eaton and Ingham Counties
Group 1 - Building Laborers
Group 2 - Mortar Mixers, hand or machine
Group 3 - Plasterer Tenders; Portable concrete mixer operator (14 and under); Air, Electric or Gasoline Tools; Tar Kettle tenders; Gasoline vibrators; Concrete gas buggies; concrete saw; Signal men and top men
Group 4 - Tunnel men; concrete shovelers; Car pushers, etc.
Group 5 - Windlass Operator (on caisson work)
Group 6 - Crock Layers (or pipe layers); Caisson workers; Tunnel muckers
Group 7 - Tunnel Miners
Jackson County
Group 1 - General Laborer
Group 2 - Jackhammer and Acetylene Torch

FOOTNOTE:
a - 5.00 per day

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LC ZONE I

LINE CONSTRUCTION WILLIAMSTON, LOCKE, LEROY, WHEATFIELD & WHITE OAK TOWN SHIPS IN INGHAM COUNTY	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen - Technician	$13.37	1.40	9%		½%
Cable Splicer	13.95	1.40	9%		½%
Combination Equipment Operator & Groundman	10.71	1.40	9%		½%
Combination Driver & Groundmen	10.08	1.40	9%		½%
Groundman	9.28	1.40	9%		½%

LC -ZONE II

LINE CONSTRUCTION: ZONE 11 REMAINING COS: & THE REMAINDER OF INGHAM CO.	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen; Heavy Equipment operator	$11.00	.45	3%	a	.5%
Cable Splicer	11.44	.45	3%	a	.5%
Combination Digger operator; Tractor operator Groundman'					
1st 6 months	7.94	.45	3%	a	.5%
Over 6 months	8.58	.45	3%	a	.5%
Light Equipment operator Groundman; Distribution Line Truck Driver Operator:					
1st 6 months	6.90	.45	3%	a	.5%
Over 6 months	7.53	.45	3%	a	.5%
Combination Winch Truck Driver Groundman:					
1st 6 months	6.28	.45	3%	a	.5%
Over 6 months	7.18	.45	3%	a	.5%
Combination Truck Driver Groundman	6.03	.45	3%	a	.5%

FOOTNOTE:
a. 7 paid Holiday; New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Day after Thanksgiving Day; and Christmas Day.

DECISION NO. MI78-2075

MICH-3-PEO-1-2

POWER EQUIPMENT OPERATORS: BUILDING & HEAVY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$12.75	.90	1.25		.05
CLASS B	12.50	.90	1.25		.05
CLASS C	12.00	.90	1.25		.05
CLASS D	11.20	.90	1.25		.05
CLASS E	11.00	.90	1.25		.05
CLASS F	9.80	.90	1.25		.05
CLASS G	9.10	.90	1.25		

CLASS A - Crane with main boom & jib 220' or longer

CLASS B - Crane with main boom & jib 140' or longer, tower cranes, gantry cranes, whirley derrick

CLASS C - Regular equipment operator, cranes, stiff leg derrick, scraper, dozer, grader, front end loader, hoist, job mechanic & head grease man

CLASS D - Air Tugger (single drum), Material Hoist, Boiler Oprs., Sweeping Machine, winch Truck, Bob Cat & Similar type equipment, Fork Truck (over 20' lift)

CLASS E - Pump 6" or over, Well Points, Freeze systems, Boom truck (non Swinging) Fork Truck (20' Lift)

CLASS F - Air Compressor, Welder, Generators, Pumps under 6", Grease Man, Conveyors

CLASS G - Oiler, Firemen & Heater Operator

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MICH-2-PEO-SE

POWER EQUIPMENT OPERATORS: STEEL ERECTION CLINTON, INGHAM & JACKSON COS.	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$11.57	.55	.75	10%	.05
CLASS B	11.33	.55	.75	10%	.05
CLASS C	10.85	.55	.75	10%	.05
CLASS D	10.70	.55	.75	10%	.05
CLASS E	9.61	.55	.75	10%	.05
CLASS F	8.65	.55	.75	10%	

CLASS A - Engineer when operation combination of boom jib 220' or longer
CLASS B - Engineer when operating combination of boom & jib 140' or longer Tower crane & derrick operator (where opeators work stations is 501 Or more above first sub level
CLASS C - Crane operator job mechanic
CLASS D - Hoisting operator
CLASS E - Compressor (or welder) operator
CLASS F - Oiler or fireman

MICH-6-PEO-SE

POWER EQUIPMENT OPERATORS: STEEL ERECTION REMAINING COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$13.10	.90	1.25		.05
CLASS B	12.85	.90	1.25		.05
CLASS C	12.35	.90	1.25		.05
CLASS D	11.55	.90	1.25		.05
CLASS E	10.30	.90	1.25		.05
CLASS F	9.55	.90	1.25		

CLASS A - Crane operator w/main boom & jib 220' or longer
CLASS B - Crane operator w/main boom & jib 140' or longer; power cranes, gantry crane; whirley derrick
CLASS C - Regular equipment operator; crane; dozer; loader; hoist, straddle wagon, Job mechanic
CLASS D - Air tugger (single drum); material hoist, pump 6' or over
CLASS E - Air compressor, welder, generators-conveyors
CLASS F - Oiler & Fireman

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MICH-8-PEO

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION CALHOUN, CLINTON, EATON, INGHAM & JACKSON COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	$10.61	.80	1.00	10%	.05
CLASS II	10.49	.80	1.00	10%	.05
CLASS III	9.83	.80	1.00	10%	.05
CLASS IV	9.31	.80	1.00	10%	.05

CLASS I - Power shovel, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip fom paver slope paver, conveyor loader (euclid type)

CLASS II - Trencher (8' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer (less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharge or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist, boom truck (power sing type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM), air compressors 600 cu. ft. per min. or larger), pumpcrete machine (and similar equipment), mechanic helper, maintenance man, boom truck(non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ dy or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propelled or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 or more up to 4" discharge if used 3 hours or more a day gas or diesel powered - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachment), finishag machine (concrete), roller (other than asphalt), curing machine (self-propelled), concrete saw (40 H.P. or over)

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MICH-9-PEO-U

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION REMAINING COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	$ 9.24	.80	1.00	10%	.05
CLASS II	8.98	.80	1.00	10%	.05
CLASS III	8.52	.80	1.00	10%	.05
CLASS IV	8.27	.80	1.00	10%	.05

CLASS I - Power shovel, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip fom paver slope paver, conveyor loader (euclid type)

CLASS II - Trencher (8' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer (less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharge or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist, boom truck (power sing type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM), air compressors 600 cu. ft. per min. or larger), pumpcrete machine (and similar equipment), mechanic helper, maintenance man, boom truck(non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ dy or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propelled or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 or more up to 4" discharge if used 3 hours or more a day gas or diesel powered - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachment), finishng machine (concrete), roller (other than asphalt), curing machine (self-propelled), concrete saw (40 H.P. or over)

SUPERSEDEAS DECISION

STATE: Michigan
DECISION NO.: MI78-2076
COUNTIES: See Below
DATE: Date of Publication
Supersedes Decision No. MI78-2014, dated March 10, 1978 in 43 FR 10208
DESCRIPTION OF WORK: Building (Does not include single family homes and garden type apartments up to and including 4 stories) and Heavy (excluding Bridge, Airport and Sewer) Construction.

COUNTIES: Bay, Genesee, Huron, Iosco, Lapeer, Saginaw, St. Clair, Sanilac, Shiawassee & Tuscola

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
St. Clair County	$ 12.15	1.35	1.39		.07
Remainder of Counties	11.85	.95	1.63		.02
BOILERMAKERS	11.95	1.18	1.10	2.00	.03
BRICKLAYERS:					
Genesee, Lapeer & Shiawassee Cos.					
Bricklayers & Stonemasons	11.50	.80	1.30		
Marble-Tile-Terrazzo Workers	10.39	.50	1.00		
St. Clair & Sanilac Counties					
Bricklayers & Stonemasons	12.33	1.15	.85		
Marble Setters	12.88	.70	1.10		
Terrazzo Workers	11.29	.60	1.00		
Tile Setters	12.41	.70	1.10		
Remainder of Counties					
Bricklayers & Stonemasons	10.94	.88	.70		
Marble-Tile-Terrazzo Workers	10.50				
CARPENTERS:					
Sanilac (Except the West 5 Miles & St. Clair Counties:					
Carpenters & Piledrivermen	11.79	.95	11%	11%	.04
Soft Floor Layers	10.72	.90	7%	8%	.03
Remainder of Counties & the West 5 Miles of Sanilac County:					
Carpenters & Piledrivermen	11.09	.60	.70		.02
Soft Floor Layers	9.28	.60	.60		.01
CEMENT MASONS:					
St. Clair & Sanilac Counties	11.51	1.15	.85		
Lapeer County	10.15	.80	1.30		
Genesee & Shiawassee Counties	10.25	.70	.60		.02
Remainder of Counties					
Cement Masonry on sidewalks, curbs & gutters not related to highway, road and street construction	10.24	.88	.70		

DECISION NO. MI78-2076

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS:					
Iosco County; Northern ½ of Co.:					
Contracts over $35,000	11.70	.50	3%+.30		1/10of1%
Contracts under $35,000	9.75	.50	3%+.30		1/10of1%
Bay Co; & Southern ½ of Iosco Co.	13.15	.40	3%+.30		½ of 1%
Genesee, Lapeer & Shiawassee Cos.	12.10	.50	3%+1.25		.02
Saginaw & Tuscola Counties	12.85		3%+1.10		½ of 1%
Remainder of Counties	13.35	1.65	3%+1.06		.03
ELEVATOR CONSTRUCTORS:					
St. Clair County:					
Constructors	12.475	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (Prob.)	50%JR				
Remainder of Counties:					
Constructors	11.21	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (Prob.)	50%JR				
GLAZIERS:					
Genesee, Lapeer & Shiawassee Cos.	9.64	.55	.70		.02
St. Clair County	9.77	.55	.65		
Bay, Huron, Isoco, Tuscola & Saginaw Cos.	9.15		.50	.25	.01
IRONWORKERS:					
Structural & Ornamental	11.18	8%	15%	17%	.09
Reinforcing	10.10	.98+.25	15%	15%	.07
Fence Erectors	10.18	8%	14%	17%	.09
LABORERS:					
Iosco County; Unksilled	6.80	.65	.40		.04
Mortar & Plaster Mixers, Sewer & Caisson Workers, Plasterer Tenders, Non-Metallic Pipe-Layers	6.95	.65	.40		.04
Cement Gun Nozzlemen, Blasters, Miners & rock Drillers	7.40	.65	.40		.04

DECISION NO. MI78-2076

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LATHERS:					
Saginaw & Genesee Counties	$ 9.92	.92	.30		.01
PAINTERS:					
Bay Iosco Cos., Huron (West of M-53) Cos., & the Townships of Akron, Almer, Columbia, Elkland, Ellington, Elmwood, Fairgrove, Gilford, Novesta, & Wisner in Tuscola County:					
Commercial	8.85	.50	.80		.02
Industiral	9.45	.50	.80		.02
Spray	9.70	.50	.80		.02
Saglanw Co., & the Remainder of Tuscola County:					
Brush	9.95		.35		.02
Spray	10.70		.35		.02
Genesee, Lapeer, & Shiawassee Cos.	9.65	.50	.70		10.00p/mo. .005
Western ½ of Shiawassee County	10.87	.42	.40		
Huron, St. Clair & Sanilac Cos.:					
Commercial & Industrial					
Brush	12.03	.55	.70		.01
Open Steel & Spray	12.58	.55	.70		.01
PLASTERERS:					
Lapeer County	10.40	.80	1.30		
Bay, Huron, Iosco, Saginaw & Tuscola Counties	10.57	.85			
Genesee & Shiawassee Cos.	10.68	.60	.50		.03
St. clair & Sanilac Counties	11.77	1.15	.85		
PLUMBERS AND STEAMFITTERS:					
Bay Iosco., N. ½ of Tuscola & the NW ¼ of Huron (running from Port Autin south to Sanilac County line)	11.34	.85	.60	1.80	
Genesee, Lapeer & Shiawassee Cos	11.47	1.00	1.10		.02
Saginaw & S. ½ of Tuscola (including Carco, Wasnjamerya and South of the Lapeer County Line Counties	11.03	.94	1.15		.02
Remainder of Huron County; St. Clair & Sanilac Counties	10.75	.25	1.30	1.52	.07

DECISION NO. MI78-2076

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ROOFERS:					
Bay, Iosco, Saginaw, & Tuscola Cos.	10.75	.85	.60		.02
Genesee, Lapeer & Shiawassee Cos					
Composition	11.45	.60	.60		
Slate & tile	11.80	.60	.60		
St. Clair, Sanilac & Huron Cos.	8.45				
SHEET METAL WORKERS:					
Bay, Iosco, Huron, Saginaw & Tuscola Counties	11.91	.80	1.00		.03
Genesee, Lapeer & Shiawassee Cos.	10.65	.79	1.20	1.00	
St. Clair & Sanilac Counties	10.550	1.66	1.52	1.16	.11
SPRINKLER FITTERS	12.37	.75	1.05		.08
TRUCK DRIVERS:					
Bay, Iosco, Saginaw & Tuscola					
Under 8 cubic yards	7.87	b26.00	b31.00	.38	
8 cubic yards & over	7.97	b26.00	b31.00	.38	
Euclid Type Equipment	8.55	b26.00	b31.00	.38	
Genessee, Lapeer & Shiawassee	8.45	b24.00	b22.00		
Huron, St. Clair & Sanilac					
Pole Trailers, Low Boys Straddle Carriers, Double Bottoms & Special Load Permit Drivers	9.90	b24.00	b28.00		
Semi Drivers	9.80	b24.00	b28.00		
All Other Truck Drivers	9.65	b24.00	b28.00		
Welders - receive rate prescribed for craft performing operation to which welding is incidcatal.					

FOOTNOTES:

a. 7 paid holidays - New Year's Day - Memorial Day - Independence Day; Labor Day; Thanksgiving Day - Day after Thanksgiving Day and Christmas Day plus employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years and 6% for employees in business less than 5 years.

b. Per Week; Per Employee, plus $3.00 per week - optical & dental

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS:					
Bay, Huron, Saginaw & Tuscola Counties					
CLASS A	$8.69	.65	.35		.04
CLASS B	8.81	.65	.35		.04
CLASS C	8.89	.65	.35		.04
CLASS D	9.46	.65	.35		.04
Genesee, Lapeer & Shiawassee Cos:					
CLASS A	8.94	.65	.55		.04
CLASS B	9.04	.65	.55		.04
CLASS C	9.14	.65	.55		.04
CLASS D	9.24	.65	.55		.04
CLASS E	9.49	.65	.55		.04
St. Clair & Sanilac Counties:					
GROUP 1	10.28	.65	.35		.04
GROUP 2	10.40	.65	.35		.04
GROUP 3	10.53	.65	.35		.04
GROUP 4	10.45	.65	.35		.04
GROUP 5	10.63	.65	.35		.04

LABORERS:

Bay, Huron, Saginaw & Tuscola Counties

CLASS A - all Construction Laborers on Building & Heavy Construction not specified in Classes, B,C, & D, below; Also includes pumps with a 3" or less discharge and not hooked up in a battery; Mechanized Buggy Operator and Motar Mixer when done by hand.

CLASS B - Mechanized Mortar Mixers; Air, electric and gas driven tools; Vibrators

CLASS C - Air or Electric driven pavement Breakers; Plasterers Tenders; Plaster Mixers; Crock and/or Pipelayers; Signal Men & Top Man; Windlass and Tugger Operator; Caisson Worker

CLASS D - Drillers & Planters; Powder

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LABORERS (CONT'D)

Genesee, Lapeer & Shiawassee Counties

CLASS A - Construction Laborers not specified in Classes B & E below

CLASS B - Mortar Mixer (includes concrete mixer ½ cu. yds. or smaller); Signal Men & Top Men (on caisson work; Air, Gasoline or Electric Tool Operators.

CLASS C - Jackhammer & Air Spade; Tunnel Menl Windlass Operators (on caisson work); Burner

CLASS D - Crock or Pipe Layers; Conduit and any Vertified Tile except 4" drain tile around Building; Caisson Workers & Tunnel Muckers

CLASS E - Tunnel Miners

St. Clair & Sanilac Counties

GROUP 1 - General Laborers; Mason Tenders; all Demolition Laborers

GROUP 2 - Mortar Mixers (Hand or Machine)

GROUP 3 - Air, Electric, Gas, Tool, Pump Operators

GROUP 4 - Concrete Gas Buggies; Concrete Saw Operators, Plasterers Tenders

GROUP 5 - Crock or Pipelayers - caisson workers in buildings

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LC-ZONE-I

LINE CONSTRUCTION HURON, LAPEER, ST. CLAIR, SANILAC & TUSCOLA COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen - Technician	$13.37	1.40	9%		½%
Cable Splicer	13.95	1.40	9%		½%
Combination equipment Operator & Groundman	10.71	1.40	9%		½%
Combination Driver-Groundman	10.08	1.40	9%		½%
Groundman	9.28	1.40	9%		½%

LC-ZONE II

LINE CONSTRUCTION: ZONE II BAY, IOSCO, GENESEE, SAGINAW & SHIAWASSEE COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen; Heavy Equipment operator	11.00	.45	3%	a	.5%
Cable Splicer	11.44	.45	3%	a	;5%
Combination Digger operator; Tractor operator Groundman:					
1st 6 months	7.94	.45	3%	a	.5%
Over 6 months	8.58	.45	3%	a	.5%
Light Equipment operator Groundman; Distribution Line Truck Driver Operator:					
1st 6 months	6.90	.45	3%	a	.5%
Over 6 months	7.53	.45	3%	a	.5%
Combination winch Truck Driver Groundman:					
1st 6 months	6.28	.45	3%	a	.5%
Over 6 months	7.18	.45	3%	a	.5%
Combination Truck Driver Groundman	6.08	.45	3%	a	.5%

Footnote: a-7 Paid Holidays; New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Day after Thanksgiving; and Christmas Day

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MICH-1-PEO-1-2

POWER EQUIPMENT OPERATORS: BUILDING & HEAVY CONSTRUCTION ST. CLAIR COUNTY	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	12.04	.80	1.00	10%	.05
CLASS B	11.81	.80	1.00	10"	.05
CLASS C	11.58	.80	1.00	10%	05
CLASS D	11.20	.80	1.00	10%	.05
CLASS E	10.05	.80	1.00	10%	.05
CLASS F	9.16	.80	1.00	10%	

CLASS A - Crane with boom & job or leads 220' or longer
CLASS B - Crane with boom and jib or leads 140' or longer
CLASS C - Regular crane operator
CLASS D - Regular Engineer
CLASS E - Engineer when operating Compressor (or welding machine)
CLASS F - Fireman or oiler

MICH -2-PEO-SE

POWER EQUIPMENT OPERATORS: STEEL ERECTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	11.57	.55	.75	10%	.05
CLASS B	11.33	.55	.75	10%	.05
CLASS C	10.85	.55	.75	10%	.05
CLASS D	10.70	.55	.75	10%	.05
CLASS E	9.61	.55	.75	10%	.05
CLASS F	8.65	.55	.75	10%	

CLASS A - Engineer when operating combination of boom jib 220' or longer
CLASS B - Engineer when operating combination of boom jib 140' or longer Tower crane & derrick operator (where operators work stations is 501 or more above first sub level
CLASS C - Crane operator job mechanic
CLASS D - Hoisting operator
CLASS E - Compressor (or welder) operator
CLASS F - Oiler or fireman

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MICH-3-PEO-1-2

POWER EQUIPMENT OPERATORS: BUILDING & HEAVY CONSTRUCTION REMAINDER OF COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$12.75	.90	1.25		.05
CLASS B	12.50	.90	1.25		.05
CLASS C	12.00	.90	1.25		.05
CLASS D	11.20	.90	1.25		.05
CLASS E	11.00	.90	1.25		.05
CLASS F	9.80	.90	1.25		.05
CLASS G	9.10	.90	1.25		

CLASS A - Crane with main boom & jib 220' or longer

CLASS B - Crane with main boom & jib 140' or longer, tower cranes, gantry cranes, whirley derrick

CLASS C - Regular equipment operator, cranes, stiff leg derrick, scraper, dozer, grader, front end loader, hoist, job mechanic & head grease man

CLASS D - Ait Tugger (single drum), Material Hoist, Boiler Oprs., Sweeping Machine,winch Truck, Bob Cat & Similar type equipment, Fork Truck (over 20' lift

CLASS E - Pump 6" or over, Well Points, Freeze systems, Boom truck (non Swinging Fork Truck (20' Lift)

CLASS F - Air Compressor, Welder, Generators, Pumps under 6", Grease Man, Conveyors

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MICH-9-PEO-U

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION IOSCO COUNTY	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	9.24	.80	1.00	10%	.05
CLASS II	8.98	.80	1.00	10%	.05
CLASS III	8.52	.80	1.00	10%	.05
CLASS IV	8.27	.80	1.00	10%	.05

CLASS I - Power shovel, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip form paver slope, paver, conveyor loader (euclid type)

CLASS II - Trencher (8' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharve or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist boom truck (power single type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM, air compressors 600 cu. ft. per min. or larger), pumperete machine (and similar equipment), mechanic helper, maintenance man, boom truck (non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ yd. or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propleeed or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 or more up to 4" discharge if used 3 hours or more a day gas or diesel powreed - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachment), finishing machine (concrete), roller (other than asphalt), curing machine (self-propelled), concrete saw (40 H.P. or over)

DECISION NO. MI78-2076

MICH-8-PEO-U

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION REMAINDER OF COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	10.61	.80	1.00	10%	.05
CLASS II	10.49	.80	1.00	10%	.05
CLASS III	9.83	.80	1.00	10%	.05
CLASS IV	9.31	.80	1.00	10%	.05

CLASS I - Power shove, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip form paver, conveyor loader (euclid type)

CLASS II - Trencher (8' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer (less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharge or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist, boom truck power single type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM), air compressors 600 cu. ft. per min. or larger), pumpcrete machine (and similar equipment), mechanic helpers, maintenance man, boom truck (non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ yd. or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propelled or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 ore more up to 4" discharge if used 3 hours or more a day gas or diesel powered - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachment, finishing machine (concrete), roller (other than asphalt), curing machine (self-propelled), concrete saw (40 H. P. or over)

STATE: Michigan

COUNTIES: Genesee, Lapeer, Saginaw, St. Clair & Shiawassee

DECISION NUMBER: MI78-2077

DATE: Date of Publication

Supersedes Decision Number MI78-2015, dated March 10, 1978 in 43 FR 10214

DESCRIPTION OF WORK: Residential Construction consisting of Single Family Homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
St. Clair County	$12.15	1.35	1.39		.07
Remainder of Counties	11.85	.95	1.63		.02
BOILERMAKERS	11.95	1.18	1.30	2.00	.03
BRICKLAYERS:					
Genesee, Lapeer & Shiawassee	11.50	.80	1.30		
Saginaw County	10.94	.88	.70		
St. Clair County	9.25	1.15	.85		
CARPENTERS:					
Saginaw County	7.67	.60	.70		.02
St. Clair County	11.79	.95	11%	11%	.04
Remainder of Counties	11.09	.60	.70		.01
CEMENT MASONS:					
Genesee & Shiawasee Counties	10.25	.70	.60		.02
Lapeer County	10.15	.80	1.30		
Saginaw County	10.24	.88	.70		
St. Clair County	8.63	1.15	.85		
ELECTRICIANS:					
Genesee, Lapeer & Shiawasee Cos.	7.28	.40	3%+.75		.02
Saginaw County	8.13		3%+.15		½ of 1%
St. Clair County	13.35	1.65	3%+1.05		.03
ELEVATOR CONSTRUCTORS:					
St. Clair County					
Constructors	12.475	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (Prob.)	50%JR				
Remainder of Counties					
Constructors	11.21	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (Prob.)	50%JR				
GLAZIERS:					
Genesee, Lapeer & Shiawassee Cs Cos.	9.64	.55	.70		.02
Saginaw County	9.15		.50	.25	.01
St. Clair County	9.77	.55	.65		
IRONWORKERS:					
Structural & Ornamental	11.18	8%	14%	17%	.09
Reinforcing	10.10	.98+.25	14%	15%	.07

DECISION NO. MI78-2077

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
LABORERS:					
Saginaw County					
Laborers; Mort. Mixers (Hand)	$ 8.69	.65	.35		.04
Plaster Mixers & Tenders	8.89	.65	.35		.04
Genesee, Lapeer & Shiawassee Cos.					
Laborers	8.94	.65	.35		.04
Air, Gas & Dlectric Tool Oprs	9.04	.65	.35		.04
Mortar Mixers	9.04	.65	.35		.04
Crock or Pipelayers	9.24	.65	.35		.04
St. Clair County					
Laborers; Mason Tenders	10.28	.65	.35		.04
Mortar Mixers	10.40	.65	.35		.04
Air, Gas & Electric Tool Oprs	10.53	.65	.35		.04
Corck or Pipelayers	10.63	.65	.35		.04
LATHERS:					
Saginaw & Genesee Cos.	9.92	.92	.30		.01
MARBLE, TILE & TERRAZZO WORKERS:					
Genesee, Lapeer & Shiawasee Cos.	10.39	.50	1.00		
Saginaw County	10.50				
St. Clair County:					
Marble Masons	12.88	.70	1.10		
Terrazzo Workers	11.29	.60	1.00		
Tile Setters	12.41	.70	1.10		
PAINTERS:					
Genesee & Eastern ½ of Counties: West of Hwy. #53 in Lapeer	9.65	.50	.70		10.00p/mo
St. Clair Co; & East of Hwy. #53 in Lapeer County	12.03	.55	.70		.01
Saginaw County	9.95		.35		.02
Western ½ of Shiawasee County	11.39	.50	.40		.0025
PLASTERERS:					
Saginaw County	11.52	.85			
Genesee & Shiawasee Counties	9.78	.50	.50		.02
Lapeer County	10.05	.50	1.00		
St. Clair County	8.82	1.15	.85		
PLUMBERS:					
Genesee, Lapeer & Shiawassee Cos.	11.47	1.00	1.10		.02
Saginaw County	11.03	.94	1.15	1.25	.02
St. Clair County	10.75	1.25	1.30	1.52	.07

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
POWER EQUIPMENT OPERATORS:					
St. Clair County					
Regular Engineer	11.20	.80	1.00	10%	.05
Regular Crane Operator	11.58	.80	1.00	10%	.05
Remainder of Counties					
Regular Equipment Operator; Scraper; Dozer; Grader, Front End Loader	12.00	.90	1.25		.05
Bob Cat & Similar Type Equip.	11.20	.90	1.25		.05
Air compressors; Generators	9.85	.90	1.25		.05
ROOFERS:					
Genesee, Lapeer & Shiawassee Cos.	11.45	.60	.60		
St. Clair County	8.45				
SHEET METAL WORKERS:					
Genesee, Lapeer & Shiawassee Cos.	10.65	.79	1.20	1.00	
Saginaw County	11.11	.65	1.00		.03
St. Clair County	10.550	1.66	1.52	1.16	.11
SOFT FLOOR LAYERS:					
St. Clair County	10.72	.90	7%	8%	.03
Remainder of County	9.28	.60	.60		.01
SPRINKLER FITTERS	12.37	.75	1.05		.08
TRUCK DRIVERS:					
Genesee, Lapeer, & Shiawassee Cos.	8.45	b24.00	b22.00		
Saginaw County					
Truck drivers	7.87	b26.00	b31.00	.38	
8 Cubic yards & over	7.97	b26.00	b31.00	.38	
Euclid Type Equipment	8.17	b26.00	b31.00	.38	
St. Clair County					
Truck Drivers	9.65	b24.00	b28.00		
Semi Trucks	9.80	b24.00	b28.00		

FOOTNOTES:

a. 7 paid Holidays - New Year's Day - Memorial Day - Independence Day - Labor Day - Thanksgiving Day - Day after Thanksgiving - Christmas Day plus employer contributes 8% of regular hourly rate to vacation pay credit for employee who has worked in business more than 5 years and 6% for employees in business less than 5 years.

b. Per week; Per Employee plus $3.00 for dental & optical

STATE: Michigan COUNTIES: *See below
DECISION NO.: MI78-2078 DATE: Date of Publication
Supersedes Decision No.: MI78-2016 dated March 10, 1978 in 43 FR 10215
DESCRIPTION OF WORK: Building Construction (Including Residential) and Heavy (Excluding Bridge, Airport and Sewer) Construction.

*Counties: Macomb, Monroe, Oakland, Washtenaw, & Wayne

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS:					
Monroe County	$13.13	.50	1.30		.04
Twps. of Bridgewater, Dexter, Freedom, Lima, Lydon, Manchester, Sharon & Sylvan in Washtenaw County	11.85	.95	1.63		.02
Remainder of Counties & the Remainder of Washtenaw County	12.15	1.35	1.39		.07
BOILERMAKERS:					
Monroe County	13.10	.70	1.00		.03
Remainder of Counties	11.955	1.18	1.20	1.50	.03
BRICKLAYERS & STONEMASONS:					
West of Hwy # 23 in Monroe Co.	11.39	.86	.55		.05
Washtenaw County	13.88		1.25		
Remainder of Counties & East of Hwy. # 23 in Monroe County	13.48	.95	8%+.20		.05
CARPENTERS & PILEDRIVERMEN					
Washtenaw County	11.94	.60	.70		.03
Remainder of Counties	11.79	.95	11%	11%	.04
CEMENT MASONS:					
South of Hwy. # 151 in Monroe County	14.14	.60			.02
Washtenaw County	13.73		1.25		
Remainder of Counties & North of Hwy. # 151 in Monroe County	11.71	.80	10%		.02
ELECTRICIANS:					
Washtenaw County	11.81	.50+4%	3%+.60	10%	3/4 of 1%
Monroe County:					
Building	13.80	.65	3%+.55		.1%
Residential	7.59	.65	3%+.55		.1%
Remainder of Counties:					
Building	13.35	1.65	3%+1.06		.03
Residential	13.35	1.65	3%+1.06		.03

DECISION NO. MI78-2078

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELEVATOR CONSTRUCTORS:					
Monroe County:					
Constructors	$12.355	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (prob.)	50%JR				
Washtenaw County					
Constructors	12.41	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (prob.)	50%JR				
Remainder of Counties					
Constructors	12.475	.745	.56	a	.025
Helpers	70%JR	.745	.56	a	.025
Helpers (prob.)	50%JR				
GLAZIERS	$ 9.77	.55	.65		
IRONWORKERS:					
Monroe County	12.87	1.06	1.22		.05
Remainder of Counties:					
Structural & Ornamental	11.18	8%	14%	17%	.09
Reinforcing	10.10	.98+.25	15%	15%	.07
Fence Erectors	10.18	8%	14%	17%	.09
Riggers & Machinery Erectors	10.50	1.25	1.98	16%	.02
LABORERS: (BUILDING, RESIDENTIAL & HEAVY)					
Monroe County:					
Construction Laborer & Carpenter helper	9.74	.55	.35	.55	.04
Mortar Mixer, Mason & Plaster Tender, Carpenter Helper, Cement Mason Helper, Tool Operator & Caisson Worker	9.94	.55	.35	.55	.04
LATHERS:					
Monroe County; excluding s/w corner-eastern portion of Washtenaw County & Remainder of Counties	10.92	.97+.35	.72		
MILLWRIGHTS:					
Washtenaw County	11.94	.60	.70		.03
Remainder of Counties	10.80	.96	11%	24%	.06

DECISION NO. MI78-2078

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
MARBLE MASONS:					
Washtenaw County	$13.88		1.25		
Remainder of Counties:					
Marble Mason	12.88	.70	1.10		
Marble Mason Finishers	10.37	.85	.80		
PAINTERS:					
Washtenaw County					
Brush	11.02	.63	.20		.02
Spray	11.77	.63	.20		.02
Tapers	11.42	.63	.20		.02
Remainder of Counties					
Brush	10.70	.74	1.00	1.00	50.00 P/Y
Spray:					
to 40' height	11.20	.74	1.00	1.00	50.00 P/Y
Over 40' height	11.325	.74	1.00	1.00	50.00 P/Y
PLASTERERS:					
South of Hwy. # 151 in Monroe Co.	13.00	.60			.01
Washtenaw County	13.88		1.25		
Remainder of Counties & Remainder of Monroe County	12.25	.85	.75		
PLUMBERS & STEAMFITTERS:					
Monroe County	11.18	.75	.80	1.25	.12
Washtenaw County	11.76	.95+.15	.75		.10
Remainder of Counties:					
Plumbers	10.75	1.25	1.30	1.52	.07
Pipefitters	10.55	1.55	1.50	1.35	.05
ROOFERS:					
Monroe County	12.63	1.06	1.00		.02
Washtenaw County:					
Composition	10.50	.85	.50	1.05	.10
Slate	11.25	.85	.50	1.05	.10
Remainder of Conties:					
Composition	11.51	.90	.90	1.10	
Slate	12.51	.90	.90	1.10	
SHEET METAL WORKERS:					
Monroe County	12.055	1.06	1.36		.045
Remainder of Counties	10.550	1.66	1.52	1.16	.11

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
SOFT FLOOR LAYERS:					
Washtenaw County	$11.94	.60	.70		.03
Remainder of Counties	10.72	.86	7%	8%	.03
SOUND & COMMUNICATION WORKERS:					
Wayne, Oakland & Macomb Cos:					
Electrical Technician	8.28	b1.60	b6.00		
Electrical Technician Jr.	6.86	b1.60	b6.00		
SPRINKLER FITTERS:					
Monroe County	12.37	.65	.95		.08
Remainder of Counties	12.185	.90	.90		.10
TILE & TERRAZZO WORKERS:					
Washtenaw County	13.47		1.00		
Remainder of Counties:					
Terrazzo Workers	11.29	.60	1.00		
Terrazzo Workers' Finishers	10.11	.60	.40	.65	
Tile Setters	12.41	.70	1.10		
Tile Setters' Finishers	9.27	.85	.80	.90	
TRUCK DRIVERS: Building & Heavy Construction:					
Pole Trailer; Low Boys; Straddle Carrier; Double Bottoms & special Load Permits	9.90	b24.00	b28.00		
Semi Drivers	9.80	b24.00	b28.00		
All Other Truck Drivers	9.65	b24.00	b28.00		
TRUCK DRIVERS: Underground Construction					
Truck Drivers (Except dump trucks of 8 cubic yards capacity or over, pole trailers, semis, low boys, Euclid, double bottom & Fuel trucks	9.08	b24.00	b28.00		
Truck Drivers on dump trucks 8 cubic yards capacity or over, Pole trailers, semis & fuel trucks	9.21	b24.00	b28.00		
Low boys, Euclid & double bottom driver	9.41	b24.00	b28.00		

FOOTNOTES: a. 7 Paid Holidays-New Years Day-Memorial Day-Independence Day-Labor Day Thanksgiving Day-Day after Thanksgiving-Christmas Day plus Employer contributes 8% of Regular Hourly Rate to Vacation Pay Credit for employee who has worked in business more than 5 years & 6% for employee in business less than 5 years.

b Per week; Per employee

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LABORERS BUILDING, RESIDENTIAL & HEAVY	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Washtenaw County:					
GROUP 1	9.14	.65	.35	1.00	.04
GROUP 2	9.34	.65	.35	1.00	.04
GROUP 3	9.46	.65	.35	1.00	.04
Wayne, Oakland & Macomb Cos:					
GROUP 1	8.93	.80	.80	.85	
GROUP 2	9.01	.80	.80	.85	
GROUP 3	9.11	.80	.80	.85	
GROUP 4	9.16	.80	.80	.85	
GROUP 5	9.18	.80	.80	.85	
GROUP 6	9.26	.80	.80	.85	
GROUP 7	9.31	.80	.80	.85	
GROUP 8	9.68	.80	.80	.85	

LABORERS: BUILDING, RESIDENTIAL & HEAVY
Washenaw County:

GROUP 1 - All Construction Laborers not specified below
GROUP 2 - Mortar mixers; Material Mixers (hand or machine) Air, Gas, Electric Tool Operators; Power Buggie Operators; Scaffold Building or Dismantler; Windlass Operators; Tar and Kettle Operators
GROUP 3 - Crock or Pipe Layers; Caisson Workers

Wayne, Oakland & Macomb Counties:

GROUP 1 - All Construction Laborers not specified below
GROUP 2 - Mortar Mixers, Scaffold Builders
GROUP 3 - Signal Men, Air gas or electric tool operators, Windlass and Tugger operator, Jackahmmer and Vibrator Operator
GROUP 4 - Crock grade man
GROUP 5 - Furnace Battery Heater Helper
GROUP 6 - Crock and Pipe Layers
GROUP 7 - Caisson Workers
GROUP 8 - Lansing Burners, Blasters, Powderman

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LABORERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
OPEN CUT CONSTRUCTION					
WASHTENAW COUNTY					
CLASS 1	7.70	.55	.35	.55	.04
CLASS 2	7.78	.55	.35	.55	.04
CLASS 3	7.83	.55	.35	.55	.04
CLASS 4	7.88	.55	.35	.55	.04
CLASS 5	7.93	.55	.35	.55	.04
WAYNE, OAKLAND, & MACOMB COS:					
CLASS 1	8.36	.75	.60	.75	.04
CLASS 2	8.44	.75	.60	.75	.04
CLASS 3	8.49	.75	.60	.75	.04
CLASS 4	8.54	.75	.60	.75	.04
CLASS 5	8.59	.75	.60	.75	.04
MONROE COUNTY					
CLASS 1	7.70	.55	.35	.55	.04
CLASS 2	7.80	.55	.35	.55	.04
CLASS 3	7.90	.55	.35	.55	.04
CLASS 4	7.95	.55	.35	.55	.04
CLASS 5	8.05	.55	.35	.55	.04

CLASS 1 - Construction Laborer
CLASS 2 - Mortar, & Material Mixers, Concrete form man, Signal Man, Wheel Point, Man, Manhole, Headwall & catch Basin Building, Guard Rail Builders & fence Erectors.
CLASS 3 - Air, gasoline, Electric Tool Ops., Vibrator Op., Drillers, Pumpman Tar Kettle Ops., bracers, rodder, Reinfroced Steel or Mesh (under 40 H.P.) Windlass & Tugger Man
CLASS 4 - Trench Excavating Grade Man
CLASS 5 - Pipelayer

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LABORERS: TUNNEL, SHAFT & CASSION CONSTRUCTION WASHTENAW & MONROE COUNTIES	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	8.33	.55	.35	.55	.04
CLASS 2	8.41	.55	.35	.55	.04
CLASS 3	8.45	.55	.35	.55	.04
CLASS 4	8.61	.55	.35	.55	.04
CLASS 5	8.81	.55	.35	.55	.04
CLASS 6	9.06	.55	.35	.55	.04
Wayne, Okaland & Macomb Cos:					
CLASS 1	8.36	.75	.60	.75	.04
CLASS 2	8.44	.75	.60	.75	.04
CLASS 3	8.94	.75	.60	.75	.04
CLASS 4	8.64	.75	.60	.75	.04
CLASS 5	8.84	.75	.60	.75	.04
CLASS 6	9.09	.75	.60	.75	.04

CLASS 1 - Tunnel, Shaft & cassion laborer, dump man, Shanty man, Hog house tender, Testing Man (on gas)
CLASS 2 - Manhole, Headwall catch basin builder, Bricklayers Tender, Mortar man, Material mixer, fence Erector & Guard rail Builder
CLASS 3 - Air Tool operator (Jackhammer man, Brush Hammer man & Grinding Man) First Bottom man, Second bottom man, Cage Tender, Car pusher, carrier man, Concrete man, concrete form man, Concrete repair man, Cement invert laborer, Cement finisher, concrete shoveler, conveyor man, Floor man, Gasoline & Electric Tool operator, Gunnite man, grout operator, Heading dinry man, inside lock tender, pea gravel operator, pump man, outside lock tender, Vibrator man, top signal man switch man, track man, Tugger man, Utility man, Vibrator man, Winch Operator, concrete saw operator (under 40 H.P.)
CLASS 4 - Tunnel, shaft & cassion mucker, Bracer man, Under Plate man, Long Haul Dinky driver & well point man
CLASS 5 - Tunnel, shaft, & Cassion Miner, Driller Runner, Key board Operator, Power Knife operator, reinforced steel or mesh man (Wire Mesh, Steel Mats, Dowell Bars, Etc.)
CLASS 6 - Dynamite man & Powerman

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LANDSCAPE LABORERS:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS "A" Landscape Specialist, including air, gas, diesel, electric tool and/or equipment	$ 6.89				
CLASS "B" Landscape Laborers, Truck Drivers, Material Haulers & Small Power Equipment	5.14				

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LINE CONSTRUCTION Wayne, Macomb, Oakland Cos; Remainder of Washtenaw & Monroe Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Linemen - Technician	$13.37	1.40	9%		½%
Cable splicers	13.95	1.40	9%		½%
Combination Equipment Operator & Groundman	10.71	1.40	9%		½%
Combination Driver-Groundman	10.08	1.40	9%		½%
Groundman	9.28	1.40	9%		½%
LINE CONSTRUCTION: Twys. of Lyndon, Manchester, Sharon & Sylvan in Washtenaw Co; Twps. of Bedford, Erie LaSalle & Whiteford in Monroe County					
Lineman; Heavy Equipment Operator	11.00	.45	3%	a	.5%
Cable Splicers	11.44	.45	3%	a	.5%
Combination Digger Operator; Tractor Operator Groundman: 1st 6 months Over 6 months	7.94 8.58	.45 .45	3% 3%	a a	.5% .5%
Light Equipment Operator Groundman; Distribution Line Truck Driver Operator: 1st 6 months Over 6 months	6.90 7.53	.45 .45	3% 3%	a a	.5% .5%
Combination Winch Truck Driver Groundman: 1st 6 months Over 6 months	6.28 7.18	.45 .45	3% 3%	a a	.5% .5%
Combination Truck Driver Groundman	6.08	.45	3%	a	.5%

FOOTNOTES:

7 paid Holidays; New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day; Day After Thanksgiving Day; and Christmas Day.

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MICH-1-PEO-1-2

POWER EQUIPMENT OPERATORS: BUILDING & HEAVY CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	12.04	.80	1.00	10%	.05
CLASS B	11.81	.80	1.00	10%	.05
CLASS C	11.58	.80	1.00	10%	.05
CLASS D	11.20	.80	1.00	10%	.05
CLASS E	10.05	.80	1.00	10%	.05
CLASS F	9.16	.80	1.00	10%	

CLASS A - Crane with boom & jib or leads 220' or longer
CLASS B - Crane with boom and jib or leads 140' or longer
CLASS C - Regular Crane Operator
CLASS D - Regular Engineer
CLASS E - Engineer when operating Compressor (or welding machine).
CLASS F - Firemen or oiler

MICH-2-PEO-SR

POWER EQUIPMENT OPERATORS: STEEL ERECTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS A	$11.57	.55	.75	10%	.05
CLASS B	11.33	.55	.75	10%	.05
CLASS C	10.85	.55	.75	10%	.05
CLASS D	10.70	.55	.75	10%	.05
CLASS E	9.61	.55	.75	10%	.05
CLASS F	8.65	.55	.75	10%	

CLASS A - Engineer when operation combination of boom jib 220' or longer
CLASS B - Engineer when operating combination of boom & jib 140' or longer Tower crane & derrick operator (where operators work stations is 501 or more above first sub level
CLASS C - Crane operator job [illegible]
CLASS D - Hoisting operator
CLASS E - Compressor (or welder) [illegible]
CLASS F - Oiler or fireman

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MICH-8-PEO-U

POWER EQUIPMENT OPERATORS: UNDERGROUND CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	10.61	.80	1.00	10%	.05
CLASS II	10.49	.80	1.00	10%	.05
CLASS III	9.83	.80	1.00	10%	.05
CLASS IV	9.31	.80	1.00	10%	.05

CLASS I - Power shovel, crane (crawler, truck type or pile driving), dragline, backhoe clamshell, trencher (over 8' digging capacity), mechanic, endloader (over 1½ cu. yd. cap.), grader, scraper (self-propelled or tractor drawn), dozer (9' blade & over), concrete paver (2 drum or larger), side boom tractor (type D-4 or equivalent & larger), elevating grader, roller (asphalt), gradall (and similar type machine), batching plant operator (concrete), backfiller tamper, well drilling rig, slip form paver slope paver, conveyor loader (euclid type)

CLASS II - Trencher (8' digging capacity & smaller), endloader (1½ cu. yd. capacity & smaller), dozer (less than 9' blade), side boom tractor (smaller than type D-4 or equivalent), pump (1 or more 6" discharge or larger - gas or diesel powered or powered by generator of 300 amps or more inclusive of generator), hoist, boom truck (power sing type boom), tractor (pneu-tired, other than backhoe or front endloader), crusher

CLASS III - Air compressor (2 or more - less than 600 CFM), air compressors 600 cu. ft. per min. or larger), pumperete machine (and similar equipment), mechanic helper, maintenance man, boom truck(non-swinging, non powered type boom), welding machine or generator (2 or more - 300 amp. or larger gas or diesel powered), pump (2 or more - 4" up to 6" discharge - gas or diesel powered - excluding submersible pumps), concrete paver (1 drum ½ yd or larger wagon drill (multiple), elevator (other than passenger), concrete breaker (self-propelled or truck mounted - includes compressor)

CLASS IV - Hydraulic pipe pushing machine, pumps (2 or more up to 4" discharge if used 3 hours or more a day gas or diesel powered - excluding submersible pumps), trencher (service), boiler, vibrating compaction equipment, self propelled (6' wide or over), stump remover, mulching equipment, farm tractor (with attachment), finishing machine (concrete), roller (other than asphalt), curing machine (self-propelled), concrete saw (40 H.P. or over)

SUPERSEDEAS DECISION

STATE: Minnesota — COUNTIES: See Below
DECISION NUMBER: MN78-2095 — DATE: Date of Publication
Supersedes Decision No. MN77-2043, dated May 6, 1978 in 42 FR 23390
DESCRIPTION OF WORK: Building (Including Residential), Construction

COUNTIES: Anoka, Carver, Hennepin, Scott, Dakota, Ramsey & Washington

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.13	.70	.65		.02
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS & STONEMASONS	10.01	.655	.53	.56	
CARPENTERS:					
Building					
S.W. Portion of Scott Co.	10.30	.40			.02
Remainder of Cos. & Scott Co. Carpenters, Millwrights & Piledrivermen	10.46	.50+.15	.50	.50	.02
Soft Floor Layers	10.10	.61	.54	.60	.02
Site Preparation, Excavation & Incidental Paving					
Paving	10.13	.60	.60		
ELECTRICIANS:					
Building					
Hennepin & Scott Cos. & Twps. of Anoka & Fridley in Anoka County					
Contracts over $50,000	11.35	7%	6%	10½%	1 3/4%
Contracts less than $50,000	9.20	7%	6%	10½%	1 3/4%
Remainder of Anoka County & Remaining Counties	11.20	5 3/4%	5 7/8%	11½%	3/8%
Residential					
Carver, Hennepin & Scott Cos; Twps. of Anoka, Fridley, Crow & Ramsey in Anoka County: Construction of all new family dwellings up to & including 4-plexes; and to all residential remodeling, rewiring & repairing in apartment buildings up to & including a 400 ampere service. This is limited to 3 floor occupied as living quarters floors, & non-elevator apartment buildings.	7.13	.48	3%	.27	1%

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS (CONT'D)					
Dakota, Ramsey, Washington Cos. & Remainder of Anoka Co.: Construction of all new family dwellings up to & including 4-plexes, townhouses of 4 or less contiguous units; and to all residential remodeling, rewiring & repairing except that any single apartment project including a change of main service entrance shall not exceed 8 living units or 400 amps.	7.35	.50	3%	.33	1/8%
ELEVATOR CONSTRUCTORS:					
Constructors	10.87	.745	.35	a	.02
Helpers	70%JR	.745	.35	a	.02
Helpers (Prob.)	50%JR				
IRONWORKERS	11.65	.75	.60		.04
LATHERS:					
Anoka, Carver & Hennepin Cos.	10.19	.50	.65		.01
Washington; Dakota & Ramsey Cos.	10.88		.50	.70	.01
MARBLE SETTERS	10.355	.555	.33		
MARBLE FINISHERS	9.35	.37	.50		
TERRAZZO WORKERS	10.79	.64	.25		
TILE SETTERS	10.75	.62	.50		
TILE FINISHERS	9.90	.62	.50		
PAINTERS:					
Dakota, Ramsey & Washington Cos:					
Brush & Drywall Finisher	10.84	.55	.25		.12
Structural Steel & Spray	11.44	.55	.25		.12
Remaining Counties:					
Brush & Roller	10.08	.55	.25		.09
Structural Steel & Spray	10.68	.55	.25		.09
PLASTERERS:					
Dakota, Ramsey & Washington Cos.	10.00	.70	.25	.65	.01
Remaining Counties	9.50	.45	.20		.01

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PLUMBERS:					
Plumbers, Steamfitters & Pipefitters:					
Dakota, Ramsey & Washington Cos.	$10.12	.48	.50	1.52	.06
Plumbers & Steamfitters & P/F Remaining Counties:					
Plumbers	10.39	.38	.50	1.35	.05
Steamfitter & Pipefitters	10.39	.38	.50	1.25	.05
ROOFERS	10.31	.69	.35		.03
SHEET METAL WORKERS:					
Dakota, Ramsey & Washington Cos.	11.86	.79	.90		.06
Remaining Counties	12.22	.52	.81		.06
SPRINKLER FITTERS	12.03	.75	1.05		.02
Welders - receive rate prescribed for craft performing operation to which welding is incidental.					

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day; G-Day After Thanksgiving

FOOTNOTE:

a. Employer contributes 8% Basic Hourly Rate for over 5 years service, 6% Basic Hourly Rate for under 5 years as Vacation Pay; 7 Paid Holidays A through G

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MINN-27-LAB-1

LABORERS: BUILDING CONSTRUCTION	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	8.30	.45	.45	.40	
CLASS 2	8.35	.45	.45	.40	
CLASS 3	8.40	.45	.45	.40	
CLASS 4	8.45	.45	.45	.40	
CLASS 5	8.55	.45	.45	.40	
CLASS 6	8.60	.45	.45	.40	
CLASS 7	8.65	.45	.45	.40	
CLASS 8	8.70	.45	.45	.40	
CLASS 9	9.005	.45	.45	.40	

CLASS 1 - Common Laborer, Steel hoist handler (erection); Power Buggy Operator, Carpenter Tender, Earth Dumpman, Flagman
CLASS 2 - Reinforced Steel Handler
CLASS 3 - Men handling cement 2 hours per day (Bulk or Sack, excluding Mortar Mixer; Mason Tender; Concrete Joint Saw Operator, Demolition & Wrecking Laborer
CLASS 4 - Hot tar caulker & corker; Laborers on swing stage line scaffold (excl. "patent" scaffolding); Automatic Tamper Operator; chipping Hammer Setter & Driver on Heavy Building, Excavation, Jackhammer Men
CLASS 5 - Underground Work
CLASS 6 - Pipelayer
CLASS 7 - Caisson Work, Underpinning
CLASS 8 - Nozzlemen
CLASS 9 - Dynamite Men, Power for Blasting purposes

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MINN-9-LAB

SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$ 8.70	.60	.45	.40	
CLASS 2	8.80	.60	.45	.40	
CLASS 3	8.85	.60	.45	.40	
CLASS 4	8.95	.60	.45	.40	
CLASS 5	9.00	.60	.45	.40	
CLASS 6	9.05	.60	.45	.40	
CLASS 7	9.10	.60	.45	.40	
CLASS 8	9.13	.60	.45	.40	
CLASS 9	9.15	.60	.45	.40	
CLASS 10	9.33	.60	.45	.40	
CLASS 11	9.38	.60	.45	.40	

CLASS 1 Unskilled Laborer, Drill Runner Helper, Landscape Gardener, Sod Layer & Nurseryman, Powder Monkey, Rein. Steel Lab., Refn. Steel Setter Salamander Heater & Blower Tender Carpenter Tender; Winch Handler
CLASS 2 Laborer, wrecking & Demolition; Bit. Batchermen (Stationary Plant); Bricklayer Tender; Cement Handler; Cement Coverman (Batch trucks); Compaction Equip. Shoveler, batchermen Conc., Conc. Vibrator Tamper & Puddler (Paving) Conc. Longitudinal Floatmen; Conduit Layer (w.o. wiring); Chipping Hammer, Surb Setter (Stone or Precast Conc.) Kettleman (BIT. or lead); Service connection maker; Power Buggy; Joint Sawer; Squeeze man (Bit. Brick or Block); Stabilizing batchermen (Stationary Plant); Stonemasons tender; Drill Runner (Heavy, including Churn Drill)
CLASS 3 Chainsaw Man, Conc. Mixer (1 bag); Jackhammer Man & Paving Buster; Mortar Mixer' Pipe Handler; Pipe Derrickman (Triped, manual)
CLASS 4 Bottom Man (Sewer, Water or Gas trench, more than 8' below starting level of manual work); Tunnel Laborer (Atmospheric pressure) Underpinning Work, Caisson Work, Oher work more than 8' below level of manual work Open ditch Work

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LABORERS: (CONT'D)

CLASS 5 - Bituminous Tamper; Pipelayers; Sand Cushion & Bedmaker
CLASS 6 - Cement Gun (1½ & over); Leadman
CLASS 7 - Nozzlemen (Gunite)
CLASS 8 - Brick or Block Paving Setter
CLASS 9 - Bituminous Raker, Floater & Utility Man
CLASS 10 - Tunnel Man (Air pressure); Tunnel Miner
CLASS 11 - Powderman

MINN-62-TD

TRUCK DRIVERS: BUILDING, SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	9.20	.40	.50		
GROUP 2	8.90	.40	.50		
GROUP 3	8.80	.40	.50		
GROUP 4	8.60	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

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MINN-1-PEO-1

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$14.60	.55	.50		.05
CLASS 2	12.95	.55	.50		.05
CLASS 3	12.70	.55	.50		.05
CLASS 4	12.10	.55	.50		.05
CLASS 5	11.75	.55	.50		.05
CLASS 6	11.65	.55	.50		.05
CLASS 7	11.40	.55	.50		.05
CLASS 8	11.28	.55	.50		.05
CLASS 9	11.20	.55	.50		.05
CLASS 10	10.93	.55	.50		.05
CLASS 11	10.45	.55	.50		.05
CLASS 12	10.00	.55	.50		.05

CLASS 1 - Helicopter Operator
CLASS 2 - Truck & Crawler Cranes with 300' of Boom and over, including jib
CLASS 3 - Truck & Crawler Cranes w/200' of Boom, up to and not including 300' of Boom, including jib
CLASS 4 - Truck & Crawler Cranes with 150' of Boom, up to and not including 200' of Boom, including jib
CLASS 5 - Traveling Tower Crane
CLASS 6 - Master Mechanic; Pile Driving Operator
CLASS 7 - Truck & Crawler Cranes up to 150' of Boom, including jib; Derrick (Guy & Stiffleg); Hoist Engineer (3 drums or more); Locomotive Operator; Overhead Crane Operator (Inside Building Perimeter); Tower Cranes - Stationary Tractor Operator with Boom; All Terrain Vehicle Cranes; Fireman, Chief License
CLASS 8 - Air Compressor Operator, 375 CFM or over; Pump Operator and/or Conveyor Opr., (2 or more machines); Hoist Engineer (two drum); Mechanic or Welder; Pumperete or Complaco-type Machine Operator; Forklift
CLASS 9 - Boom Truck Operator; Concrete Mixer Operator; Drill Rigs - Heavy Rotary or Churn when used for caisson drilling for Elevator Cylinder or Building Construction; Front End loader Operator; Hoist Engineer (one drum); Straddle Carrier Operator; Power Plant Engineer (100 KW and over on miltiples equal to 100 KW and over); Tractor Operator over D2; Well Point Pump Operator
CLASS 10 - Concrete Batch Plant Operator; Fireman, First Class License; Gunite Operator; Tractor Operator D-2 or similar size; Front End Loader Operator, up to 1 cu. yd.
CLASS 11 - Air Compressor Opr., 375 CFM or over; Pump and/or Conveyor Opr.; Fireman, Temporary Heat; Brakeman; Pick-up Sweeper (1 cu. yd. and over hopper capacity); Truck Crane Oiler; Welding Machine Opr. (see Schedule 16 on Air Comp., Pumps, Conveyors, Welding Mach.
CLASS 12 - Mechanical Space Heater (Temporary Heat); Oiler or Greaser; Elevator Operator

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MINN-7M-PEO-2-3

SITE PREPARATION, EXCAVATION & INCIDENTAL PAVING

POWER EQUIPMENT OPERATORS:

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.75	.55	.50		.05
GROUP 2	11.46	.55	.50		.05
GROUP 3	11.15	.55	.50		.05
GROUP 4	11.02	.55	.50		.05
GROUP 5	10.93	.55	.50		.05
GROUP 6	10.15	.55	.50		.05
GROUP 7	10.05	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derr, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumperete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, Fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Launcherman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty might or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

DECISION NO. MN78-2095

POWER EQUIPMENT OPERATORS: (CONT'D)

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

STATE: Minnesota

COUNTIES: Blue Earth, Fairbault, Freeborn & Mower

DECISION NUMBER: MN78-2096

DATE: Date of Publication

Supersedes Decision NO. MN77-2044, Dated May 6, 1977 in 42 FR 23395

DESCRIPTION OF WORK: Building Construction (Including Residential), Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.13	.70	.65		.02
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS:					
Blue Earth County					
Bricklayers, Stonemasons & Blocklayers	9.855	.50	.51	.61	
Mower County & that part of Freeborn Co., east of a line running north & south from Geneva to Gordon & the City of Blooming Prairie:					
Bricklayers, Stonemasons, Cement Blocklayers, Pointers, Caulkers & Cleaners	10.575	.50	.25		
Fairbault & Remainder of Freeborn County					
Bricklayers, Stonemasons, Tuck Pointers & Blocklayers	10.18	.57	.25		
CARPENTERS:					
Building:					
Blue Earth County					
N. W. Portion of County	10.20				
Remainder of County	10.90	.50			.02
Freeborn & Fairbault Counties					
Carpenters, Millwrights & Piledrivermen	10.12				
Mower County					
Carpenters & Piledrivermen	10.12				
Site Preparation, Excavating & Incidental Paving					
Blue Earth County	7.32	.30			
Fairbault, Freeborn & Mower Cos.	8.48				
CEMENT MASONS & PLASTERERS:					
Building:					
Blue Earth County					
Cement Masons	10.10				
Plasterers	9.40				
Mower County & that part of Freeborn Co., east of a line running north & south from Geneva to Gordon:					
Cement Masons & Plasterers	9.35	.50	.25		

CEMENT MASONS (CONT'D)	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Fairbault Co., & Remainder of Freeborn No.:					
Cement Masons & Plasterers	$ 9.28	.57	.25		
Site preparation, Excavation & Incidential Paving					
Blue Earth County	10.10				
Fairbault Co.; Freeborn Co: (West of a line running North & South from Geneva to Gordonsville)	9.43	.42	.25		
Mower Co. & Remainder of Freeborn County	9.50	.35	.25		
ELECTRICIANS:					
Blue Earth & Fairbault Counties					
Jobs outside the Mankato City Area less than $50,000	8.45	7½%	6%	10%	1%
Jobs within a 5 mile radius of Mankato $50,000 & over	10.60	7½%	6%	10%	1%
Freeborn & Mower Counties $75,000 or more	10.65	.60	3%	6%	.25%
$75,000 or less & Residential	8.52	.60	3%	6%	.25%
ELEVATOR CONSTRUCTORS:					
Blue Earth County					
Constructors	10.87	.745	.35	a	.02
Helpers	70%JR	.745	.35	a	.02
Helpers (Prob.)	50%JR				
GLAZIERS:					
Blue Earth County	8.20				
Remainder of Counties	10.00				
IRONWORKERS	11.65	.75	.60		.04
LABORERS: Building					
General Laborers & Carp. Tender	8.50	.20	.15		
Mason tenders & Vibrator Oprs.	8.60	.20	.15		
Mortar Mixers	8.65	.20	.15		
MARBLE-TILE-TERRAZZO WORKERS:					
Marble Setters	10.765	.565	.33		
Terrazzo Workers	10.74	.64	.25		
Tile Setters	10.17	.62	.50		
Marble Setters' Finishers	9.75	.37	.50		
Tile Setters Finishers	9.29	.62	.50		

DECISION NO. MN78-2096

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
Mower County					
Brush	$ 9.50	.37	.25		.08
Spray	10.00	.37	.25		.08
Remainder of Counties					
Brush	9.90	.60	.15		.11
Spray	10.40	.60	.15		.11
Structural Steel	10.90	.60	.15		.11
PLUMBERS & STEAMFITTERS:					
Blue Earth County	11.72	.53			.05
Remainder of Counties	11.61	.30	.20		.02
ROOFERS:					
Mower County	9.62		.20		
Remainder of Counties	9.95	.55			
SHEET METAL WORKERS	10.74	.52	.33		
SPRINKLER FITTERS	11.93	.75	1.05		.08
TRUCK DRIVERS	8.50				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental.					

FOOTNOTES:

a. Employer contributes 8% BHR for over 5 years service & 6% BHR for under 5 years service as Vacation Pay. Seven Paid Holidays: New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day and Christmas Day and Day after Thanksgiving

DECISION NO. MN78-2096

MINN-12-LAB

LABORERS: SITE PREPARATION, EXCAVATION & INCIDENTAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$ 8.90	.35	.15		
CLASS 2	9.00	.35	.15		
CLASS 3	9.05	.35	.15		
CLASS 4	9.15	.35	.15		
CLASS 5	9.25	.35	.15		
CLASS 6	9.30	.35	.15		
CLASS 7	9.35	.35	.15		
CLASS 8	9.40	.35	.15		

CLASS 1 - Unskilled Laborers, Bricklayer & Carpenter Tenders; Drill Runner Helper; Laborers-Wrecking & Demolition; Landscape Gardner; Pipe Handler (Water, Gas, Cast Iron); Salamander Heater & Blower Tender; Sod; Sod Layer & Nurseryman, Stonemason Tender.

CLASS 2 - Bituminous Shoveler; Bottom Man (Sewer, Water or Gas Trench); Cement Coverman (Batch Trucks); Cement Handler (Bulk or bag) Chain Saw Shoveler; Tamper & Puddler (Paving); Concrete Vibrator; Conduit Layers (w/o wiring); Drill Runner (Heavy, incl. Churn Drill) Dumper (wagon, Truck Jackhammerman; Joint Sawyer, Kettlemen (Bituminous or Lead); Mortar Mixers; Paving Buster; Power Buggy; Tunnel Laborer (Atomspheric Pressure).

CLASS 3 - Bituminous Tamper

CLASS 4 - Bituminous Raker; Floater & Utility Man; Caisson Work; Cofferdam

CLASS 5 - Leadman

CLASS 6 - Nozzle (Gunnite)

CLASS 7 - Pipelayer (Sewer, Water & Gas)

CLASS 8 - Powderman

DECISION NO. MN78-2096

MINN-1-PEO-1

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$14.60	.55	.50		.05
CLASS 2	12.95	.55	.50		.05
CLASS 3	12.70	.55	.50		.05
CLASS 4	12.10	.55	.50		.05
CLASS 5	11.75	.55	.50		.05
CLASS 6	11.65	.55	.50		.05
CLASS 7	11.40	.55	.50		.05
CLASS 8	11.28	.55	.50		.05
CLASS 9	11.20	.55	.50		.05
CLASS 10	10.93	.55	.50		.05
CLASS 11	10.45	.55	.50		.05
CLASS 12	10.00	.55	.50		.05

CLASS 1 - Helicopter Operator
CLASS 2 - Truck & Crawler Cranes with 300' of Boom and over, including jib
CLASS 3 - Truck & Crawler Cranes w/200' of Boom, up to and not including 300' of Boom, including jib
CLASS 4 - Truck & Crawler Cranes with 150' of Boom, up to and not including 200' of Boom, including jib
CLASS 5 - Traveling Tower Crane
CLASS 6 - Master Mechanic; Pile Driving Operator
CLASS 7 - Truck & Crawler Cranes up to 150' of Boom, including jib; Derrick (Guy & Stiffleg); Hoist Engineer (3 drums or more); Locomotive Operator; Overhead Crane Operator (Inside Building Perimeter); Tower Cranes - Stationary Tractor Operator with Boom; All Terrain Vehicle Cranes; Fireman, Chief License
CLASS 8 - Air Compressor Operator, 375 CFM or over; Pump Operator and/or Conveyor Opr., (2 or more machines); Hoist Engineer (two drum); Mechanic or Welder; Pumperete or Compiaco-type Machine Operator; Forklift
CLASS 9 - Boom Truck Operator; Concrete Mixer Operator; Drill Rigs - Heavy Rotary or Churn when used for caisson drilling for Elevator Cylinder or Building Construction; Front End loader Operator; Hoist Engineer (one drum); Straddle Carrier Operator; Power Plant Engineer (100 KW and over on miltiples equal to 100 KW and over); Tractor Operator over D2; Well Point Pump Operator
CLASS 10 - Concrete Batch Plant Operator; Fireman, First Class License; Gunite Operator; Tractor Operator D-2 or similar size; Front End Loader Operator, up to 1 cu. yd.
CLASS 11 - Air Compressor Opr., 375 CFM or over; Pump and/or Conveyor Opr.; Fireman, Temporary Heat; Bituminous Pick-up Sweeper (1 cu. yd. and over hopper capacity); Truck Crane Oiler; Pile[illegible] Machine Opr. (see Schedule 16 on Air Comp., Pumps, Conveyors, Welding Mach.
CLASS 12 - Mechanical Spray Heater (Temporary Heat); Oiler or Greaser; Elevator Operator

DECISION NO. MN78-2096

MINN-6-PEO

POWER EQUIPMENT OPERATORS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.45	.55	.50		.05
GROUP 2	11.16	.55	.50		.05
GROUP 3	10.85	.55	.50		.05
GROUP 4	10.73	.55	.50		.05
GROUP 5	10.63	.55	.50		.05
GROUP 6	10.25	.55	.50		.05
GROUP 7	9.75	.55	.50		.05

GROUP 1 - Helicopter Pilot
GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rated capacity
GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rated capacity, Dredge Operator or Engineer, dredge Oper. (power) & Engineer, Front End Loader Op., 5 cu. yds. & over, Grader or Motor Patrol, Finishing earthwork & bituminous, Locomotive Crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over
GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumperete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer
GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, fork Lift or Straddle carrier Op., Fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Lumberman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty might or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, 75% or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (power, water, gas) turnapull op., (or similar type) well point installation, dismantling or repair mechanic

DECISION NO. MN78-2096

POWER EQUIPMENT OPERATORS: (CONT'D)

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrc , gunite op. gunall, lead greader on truck or rack, loaderop., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman, conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

DECISION NO. MN78-2096

MINN-5-TD

TRUCK DRIVERS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING Fairbault County	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$ 8.02	.40	.50		
GROUP 2	7.72	.40	.50		
GROUP 3	7.62	.40	.50		
GROUP 4	7.42	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

DECISION NO. MN78-2096

MINN-7-TD

TRUCKD RIVERS: SITE PREPARATION, EXCAVATING & INCIDENTIAL PAVING Blue Earth County	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$ 8.62	.40	.50		
GROUP 2	8.32	.40	.50		
GROUP 3	8.22	.40	.50		
GROUP 4	8.02	.40	.50		

GROUP 1 - Drive (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

DECISION NO. MN78-2096

MINN-55-TD

SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING Freeborn & Mower Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$ 9.15	.40	.50		
GROUP 2	8.85	.40	.50		
GROUP 3	8.75	.40	.50		
GROUP 4	8.55	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

SUPERSEDEAS DECISION

STATE: Minnesota COUNTY: Olmsted
DECISION NUMBER: MN78-2097 DATE: Date of Publication
Supersedes Decision No. MN77-2045, Dated May 6, 1977 in 42 FR 23400
DESCRIPTION OF WORK: Building (Including Residential) Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.13	.70	.65		.02
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS:					
Bricklayers; Stonemasons; Cement Blocklayers; Pointers; Caulkers & Cleaners	10.575	.50	.25		
CARPENTERS:					
Building	9.50	.50	.50		
Site Preparation, Excavation & Incidential Paving					
Carpenters & Piledrivermen	7.88	.50	.20		
CEMENT MASONS:					
Building	9.35				
Site Preparation, Excavation & Incidential Paving	10.35				
ELECTRICIANS					
$25,000 or more	10.01	.44	3%	6%	.25%
Under $25,000 & Residential	7.67	.44	3%	6%	.25%
GLAZIERS	10.06			.30	
IRONWORKERS	11.65	.75	.60		.04
LABORERS:					
General Laborer; Carpenter Tender; Flagman; Power Buggy Operator	8.50	.20	.15		
Mason Tender; Drill Runner; Vibrator Operator; Rebar Laborer	8.60	.20	.15		
Mortar Mixer; Air Acutated Tool	8.65	.20	.15		
Plasterer Tender	8.75	.20	.15		
Nozzleman	8.90	.20	.15		
LATHERS	10.50				
MARBLE SETTERS	10.335	.555	.33		
PAINTERS:					
Brush	9.50	.37	.25		.08
Spray, Swing Stage & High Work	10.00	.37	.25		.08

DECISION NO. MN78-2097

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PLASTERERS	9.35	.50	.25		
PLUMBERS & STEAMFITTERS	11.61	.30	.20		.02
ROOFERS	9.40	.42	.33		
SHEET METAL WORKERS	10.74	.52	.33		.02
SPRINKLER FITTERS	11.93	.75	1.05		.08
TILE SETTERS	10.72				
TRUCK DRIVERS -	8.50				
Welders - Receive rate prescribed for craft performing operation to which welding is incidental.					

DECISION No. MN78-2097

MINN-12-LAB

LABORERS: SITE PREPARATION, EXCAVATION & INCIDENTAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$ 8.90	.35	.15		
CLASS 2	9.00	.35	.15		
CLASS 3	9.05	.35	.15		
CLASS 4	9.15	.35	.15		
CLASS 5	9.25	.35	.15		
CLASS 6	9.30	.35	.15		
CLASS 7	9.35	.35	.15		
CLASS 8	9.40	.35	.15		

CLASS 1 - Unskilled Laborers, Bricklayer & Carpenter Tenders; Drill Runner Helper; Laborers-Wrecking & Demolition; Landscape Gardner; Pipe Handler (Water, Gas, Cast Iron); Salamander Heater & blower Tender; Sod Layer & Nurseryman, Stonemason Tender.
CLASS 2 - Bituminous Shoveler; Bottom Man (Sewer, Water or Gas Trench); Cement Coverman (Batch Trucks); Cement Handler (Bulk or bag) Chain Saw Shoveler; Tamper & Puddler (Paving); Concrete Vibrator; Conduit Layers (w/o wiring); drill Runner (Heavy, incl. Churn Drill) Dumper (wagon, Truck Jackhammerman; Joint Sawyer, Kettlemen (Bituminous or Lead); Mortar Mixers; Paving Buster; Power Buggy; Tunnel Laborer (Atmospheric Pressure).
CLASS 3 - Bituminous Tamper
CLASS 4 - Bituminous Raker; Floater & Utility Man; Caisson Work; Cofferdam
CLASS 5 - Leadman
CLASS 6 - Nozzle (Gunnite)
CLASS 7 - Pipelayer (Sewer, Water & Gas)
CLASS 8 - Powderman

DECISION NO. MN78-2097

MINN-1-PEO-1

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$14.60	.55	.50		.05
CLASS 2	12.95	.55	.50		.05
CLASS 3	12.70	.55	.50		.05
CLASS 4	12.10	.55	.50		.05
CLASS 5	11.75	.55	.50		.05
CLASS 6	11.65	.55	.50		.05
CLASS 7	11.40	.55	.50		.05
CLASS 8	11.28	.55	.50		.05
CLASS 9	11.20	.55	.50		.05
CLASS 10	10.93	.55	.50		.05
CLASS 11	10.45	.55	.50		.05

CLASS 1 - Helicopter Operators (Hoisting Material)
CLASS 2 - Truck & crawler Cranes with 200' of Boom & over including Jib
CLASS 3 - Truck & crawler Cranes with 150' of Boom up to & not including 200' of Boom including jib.
CLASS 4 - Traveling Tower Crane
CLASS 5 - Master Mechanic
CLASS 6 - Derrick (Guy & Stiff Leg); Hoist engineer (3 drums or more); Locomotive Operator; Overhead Crane Operator, (inside Building Perimeter); Truck & Crawler Cranes up to 150' of Boom including jib.
CLASS 7 - Air compressor Operator; Pump & or Conveyor; 2 or more Mechanics; Hoist engineer (2 drum); Mechanic or welder; Pumperete or Complaco type Machine Operator; Fork Lift Operator
CLASS 8 - Boom truck Operator; Concrete Mixer Operator; Drill Rigs (Heavy Duty Rotary or Churn Drill when used for caisson drilling or when drilling for elevator cylinder or Building Construction; Front End Loader Opr., Hoist Engineer (1 drum); Power Plant Engineer (100 KWH & over); Straddle carrier Operator; Tractor Operator (over D-2); Well Point Pump Operator
CLASS 9 - Concrete Batch Plant Operator; gunnite Operator; Tractor Operator (D-2 or similar size 7 Front End Loader Operator-up to ½ cu. yd.)
CLASS 10 - Air Compressor Operator; Pump & or Conveyor Operator; Fireman-Temporary Heat; Brakeman; Pick Up Sweeper (combustion engine operated); Truck Crane Oiler
CLASS 11 - Mechanic Space Heater (Temporary Heat) Oiler or Greaser

DECISION NO. MN78-2097 MINN-6-PEO

POWER EQUIPMENT OPERATORS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.45	.55	.50		.05
GROUP 2	11.16	.55	.50		.05
GROUP 3	10.85	.55	.50		.05
GROUP 4	10.73	.55	.50		.05
GROUP 5	10.63	.55	.50		.05
GROUP 6	10.25	.55	.50		.05
GROUP 7	9.75	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conmy or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, Fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Launchman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty might or similar type), Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 H. without power take-off, trenching machine Op., (power, water, gas) turntable op.,(or similar type) well point installation, dismantling or repair mechanic

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POWER EQUIPMENT OPERATORS: (CONT'D)

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

DECISION NO. MN78-2097

MINN-55-TD

TRUCK DRIVERS: SITE PREPARATION, EXCAVATION & INCIDENTAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$9.15	.40	.50		
GROUP 2	8.85	.40	.50		
GROUP 3	8.75	.40	.50		
GROUP 4	8.55	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

SUPERSEDEAS DECISION

STATE: Minnesota COUNTIES: Benton, Sherburne & Stearns
DECISION NUMBER: MN78-2098 DATE: Date of Publication
Supersedes Decision No. MN77-2046, dated May 6, 1978, in 42 FR 23404
DESCRIPTION OF WORK: Building (Including Residential), Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.13	.70	.65		.02
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS & STONEMASONS	10.40		.25	1.00	
CARPENTERS:					
Building Construction					
Southern tip of Sherburne Co.					
Carpenters, Millwrights & Piledrivermen	10.46	.65	.50	.50	.02
Soft Floor Layers	10.10	.61	.54	.45	.02
Cities of Little Rock & Skate in Benton County					
Carpenter	9.35				
Stearns Co., Remainder of Benton & Sherburne Counties					
Carpenters & Piledrivermen	10.08			.75	
Soft Floor Layers	7.50				
Site Preparation, Excavation & Incidental Paving					
Sherburn Co.; Northern Bondary of T-34-N & East of the Western Boundary of R-27-W	8.21	.40	.30	.50	.02
Benton Co., Stearns Co. (East of A North-South Line Drawn from the intersection of Stearns, Todd & Morrison Cos.) & the remainder of Sherburne Co.	7.47			.75	
Remainder of Stearns County	7.62				
CEMENT MASONS:					
Building Construction					
Benton & Stearns Counties					
Cement Masons & Plasterers	9.55		.25	.35	
Sherburne County					
Cement Masons	10.13	.60	.60		
Plasterers	10.00	.70	.25	.65	.01
Site Preparation, Excavation & Incidental Paving					
Sherburne County		.60	.60		
Benton & Stearns Counties				.25	

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELECTRICIANS:					
Benton & Stearns Cos.; Twps. of Haven, Palmer, Santiago, Becker & Clear Lake in Sherburne County:					
Jobs under $50,000	8.45	7½%	6%	10%	1⅛
Jobs over $50,000	10.60	7½%	6%	10%	1⅛
Remainder of Sherburne County	11.20	5 3/4%	5 7/8%	11¼%	3/8%
GLAZIERS	10.03	.40			
IRONWORKERS	11.65	.75	.60		.04
LABORERS:					
Building Construction Stearns & Benton Counties:					
General Laborers, Demolition & Wrecking; Concrete Joint Saw Opr.; Signal Men	8.30	.20	.15		
Power Buggy Operators	8.35	.20	.15		
Mortar Mixers; Plasterer Tenders	8.40	.20	.15		
Jackhammer Men	8.45	.20	.15		
Underground; Caisson; Cofferdam & Tunnel work	8.55	.20	.15		
Dynamite Men	8.60	.20	.15		
Sherburne County:					
Common, Carpenter Tender	8.30	.45	.45	.40	
Wrecking & demolition	8.40	.45	.45	.40	
Vibrator Opr; Jackhammermen; Mortar Mixers	8.45	.45	.45	.40	
Underground Work	8.55	.45	.45	.40	
Pipelayers	8.60	.45	.45	.40	
Caisson Work - Underpinning	8.65	.45	.45	.40	
Dynamite Men	9.005	.45	.45	.40	
LATHERS:					
Benton & Stearns Counties	10.19	.50	.65	.01	
MARBLE SETTERS	10.355	.555	.33		

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
Eastern 2/3 of Sherburne County:					
Brush, Roller & Paperhangers	$10.08	.55		.25	.09
Spray, Structural Steel & Sandblasting	10.68	.55		.25	.09
Benton, & Stearns Counties & the Remainder of Sherburne County:					
Residential	8.50			3%	
Brush	7.90			3%	
Structural Steel	8.40			3%	
Spray	8.90			3%	
PLUMBERS & STEAMFITTERS:					
Sherburne County:					
Plumbers Eastern ½ of County	10.39	.38	.50	1.35	.05
Steamfitters Eastern ½ of County	10.39	.38	.50	1.25	.05
Benton & Stearns Cos. & the Western ½ of Sherburne Co:					
Plumbers & Steamfitters	11.82	.53	.50		.06
ROOFERS:					
Roofers	8.90	.64	.25		
SHEET METAL WORKERS	11.52	.52	.31		.03
SPRINKLER FITTERS	11.93	.75	1.05		.08
TRUCK DRIVERS - Building	8.30				
WELDERS - receive rate prescribed for craft performing operation to which welding is incidental					

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MINN-9-LAB

SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING

LABORERS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Sherburne County					
CLASS 1	$ 8.70	.60	.45	.40	
CLASS 2	8.80	.60	.45	.40	
CLASS 3	8.85	.60	.45	.40	
CLASS 4	8.95	.60	.45	.40	
CLASS 5	9.00	.60	.45	.40	
CLASS 6	9.05	.60	.45	.40	
CLASS 7	9.10	.60	.45	.40	
CLASS 8	9.13	.60	.45	.40	
CLASS 9	9.15	.60	.45	.40	
CLASS 10	9.33	.60	.45	.40	
CLASS 11	9.38	.60	.45	.40	

CLASS 1 Unskilled Laborer, Drill Runner Helper, Landscape Gardener, Sod Layer & Nurseryman, Powder Monkey, Rein. Steel Lab., Rein. Steel Setter Salamander Heater & Blower Tender Carpenter Tender; Winch Handler

CLASS 2 Laborer, wrecking & Demolition; Bit. Batchermen (Stationary Plant); Bricklayer Tender; Cement Handler; Cement Coverman (Patch trucks); Compaction Equip. Shoveler, batcherman Conc., Conc. Vibrator Tamper & Puddler (Paving) Conc. Longitudinal Floatmen; Conduit Layer (w.o. wiring); Chipping Hammer, Surb Setter (Stone or Precast Conc.) Kettleman (Bit. or lead); Service connection maker; Power Buggy; Joint Sawer; Squeeze man (Bit. Brick or Block); Stabilizing batcherman (Stationary Plant); Stonemasons tender; Drill Runner (Heavy, including Churn Drill)

CLASS 3 Chainsaw Man, Conc. Mixer (1 bag); Jackhammer Man & Paving Buster; Mortar Mixer' Pipe Handler; Pipe Derrickman (Tripod, manual)

CLASS 4 Bottom Man (Sewer, Water or Gas trench, more than 9' below starting level of manual work); Tunnel Laborer (Atmospheric pressure) Underpinning Work, Caisson Work, Other work more than 8' below level of manual work Open ditch Work

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LABOREPS: (CONT'D)

CLASS 5 - Bituminous Tamper; Pipelayers; Sand Cushion & Bedmaker
CLASS 6 - Cement Gun (1½ & over); Leadman
CLASS 7 - Nozzlemen (Gunite)
CLASS 8 - Brick or Block Paving Setter
CLASS 9 - BITUminous Raker, Floater & Utility Man
CLASS 10 - Tunnel Man (Air pressure); Tunnel Miner
CLASS 11 - Powderman

DECISION NO. MN78-2098

MINN-11-LAB

LABORERS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Benton & Stearns Counties					
CLASS 1	$ 8.15	.55	.35	.40	
CLASS 2	8.20	.55	.35	.40	
CLASS 3	8.25	.55	.35	.40	
CLASS 4	8.30	.55	.35	.40	
CLASS 5	8.40	.55	.35	.40	
CLASS 6	8.70	.55	.35	.40	
CLASS 7	8.75	.55	.35	.40	
CLASS 8	8.80	.55	.35	.40	

CLASS 1 - Bricklayer Tender, Carpenter, Drill Runner Helper, Laborers-Wrecking & Demolition, Landscape Gardner, Pipe Handler (Water, Gas & Cast Iron); Salamander Heater & Blower Tender, Sod Layer & Nurseryman; Stonemason Tenders; Unskilled Laborers

CLASS 2 - Form Setter (Municipal Type Curb & Sidewald, Form Setter (Pavement) coverman (Batch Trucks); Cement Handler (Bulk or Bag); chain Saw Man; Compaction equipment (Hand operated); Concrete Mixer (1 Bag); Concrete Shoveler Tamper & Puddler (Paving); Concrete Vibrator; Conduit Layers (w/o wiring); Drill Runner (wagon, Truck, etc.); Jackhammerman, Joint Sawer, Kettleman (Bituminous or Lead); Mortar Mixers, Paving Buster, Power Buggy, Tunnel Laborer (Atmospheric pressure)

CLASS 4 - Bituminous Raker, Floater & Utility Man;, Caisson work, Cofferdam

CLASS 5 - Leadman

CLASS 6 - Gunnite

CLASS 7 - Pipelayer (Sewer, Water & Gas)

CLASS 8 - Powderman, Tunnel Miner

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MINN-1-PEO-1

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$14.60	.55	.50		.05
CLASS 2	12.95	.55	.50		.05
CLASS 3	12.70	.55	.50		.05
CLASS 4	12.10	.55	.50		.05
CLASS 5	11.75	.55	.50		.05
CLASS 6	11.65	.55	.50		.05
CLASS 7	11.40	.55	.50		.05
CLASS 8	11.28	.55	.50		.05
CLASS 9	11.20	.55	.50		.05
CLASS 10	10.93	.55	.50		.05
CLASS 11	10.45	.55	.50		.05
CLASS 12	10.00	.55	.50		.05

CLASS 1 - Helicopter Operator

CLASS 2 - Truck & Crawler Cranes with 300' of Boom and over, including jib

CLASS 3 - Truck & Crawler Cranes w/200' of Boom, up to and not including 300' of Boom, including jib

CLASS 4 - Truck & Crawler Cranes with 150' of Boom, up to and not including 200' of Boom, including jib

CLASS 5 - Traveling Tower Crane

CLASS 6 - Master Mechanic; Pile Driving Operator

CLASS 7 - Truck & Crawler Cranes up to 150' of Boom, including jib; Derrick (Guy & Stiffleg); Hoist Engineer (3 drums or more); Locomotive Operator; Overhead Crane Operator (Inside Building Perimeter); Tower Cranes - Stationary Tractor Operator with Boom; All Terrain Vehicle Cranes; Fireman, Chief License

CLASS 8 - Air Compressor Operator, 375 CFM or over; Pump Operator and/or Conveyor Opr., (2 or more machines); Hoist Engineer (two drum); Mechanic or Welder; Pumperete or Complaco-type Machine Operator; Forklift

CLASS 9 - Boom Truck Operator; Concrete Mixer Operator; Drill Rigs - Heavy Rotary or Churn when used for caisson drilling for Elevator Cylinder or Building Construction; Front End loader Operator; Hoist Engineer (one drum); Straddle Carrier Operator; Power Plant Engineer (100 KW and over on miltiples equal to 100 KW and over); Tractor Operator over D2; Well Point Pump Operator

CLASS 10 - Concrete Batch Plant Operator; Fireman, First Class License; Gunite Operator; Tractor Operator D-2 or similar size; Front End Loader Operator, up to 1 cu. yd.

CLASS 11 - Air Compressor Opr., 375 CFM or over; Pump and/or Conveyor Opr.; Fireman, Temporary Heat; Brakeman; Pick-up Sweeper (1 cu. yd. and over hopper capacity); Truck Crane Oiler; Welding Machine Opr. (see Schedule 10 on Air Comp., Pumps, Conveyors, Welding Mach.

CLASS 12 - Mechanical Spud Heater (Temporary Heat); Oiler or Greaser; Elevator Operator

DECISION NO. MN78-2098

SITE PREPARATION, EXCAVATION & INCIDENTAL PAVING

MINN-7M-DEC-2-3

POWER EQUIPMENT OPERATORS: Sherburne Co. (South of the Northern Boundary of T-33-N & East of the Western Boundary of R-27-W	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.75	.55	.50		.05
GROUP 2	11.46	.55	.50		.05
GROUP 3	11.15	.55	.50		.05
GROUP 4	11.02	.55	.50		.05
GROUP 5	10.93	.55	.50		.05
GROUP 6	10.15	.55	.50		.05
GROUP 7	9.75	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumperete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Maint Engineer, Hydraulic Tree Planter, Lamplerman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty Might or similar type, Pick-up

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POWER EQUIPMENT OPERATORS (CONT'D)

GROUP 5 (Cont'd)

sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFM or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augers and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser laverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

DECISION NO. MN78-2098 MINN-6-PEO

POWER EQUIPMENT OPERATORS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Stearns Co; (East of the Western Right-of-Way of Minn. Hwy. 15) Benton Co.: (East of the Western Right-of-Way of Hwy. 10) & Remainder of Sherburne Co.					
GROUP 1	$14.45	.55	.50		.05
GROUP 2	11.16	.55	.50		.05
GROUP 3	10.85	.55	.50		.05
GROUP 4	10.73	.55	.50		.05
GROUP 5	10.63	.55	.50		.05
GROUP 6	9.85	.55	.50		.05
GROUP 7	9.45	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Trqboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, Fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Lumberman, Tabsetter, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or Pugmill

DECISION NO. MN78-2098

(POWER EQUIPMENT OPERATORS) (CONT'D)

GROUP 5 (Cont'd)

machines op., (power-driven - Mighty might or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & hallast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., Sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

DECISION NO. MN78-2098

MINN-7-PEO

POWER EQUIPMENT OPERATORS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING Remainder of Benton & Stearns Cos.	Basic Hourly Rates	Fringe Benefits Payments			
		H.& W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.00	.55	.50		.05
GROUP 2	9.82	.55	.50		.05
GROUP 3	9.32	.55	.50		.05
GROUP 4	9.18	.55	.50		.05
GROUP 5	9.10	.55	.50		.05
GROUP 6	8.57	.55	.50		.05
GROUP 7	8.17	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over, Mfg. rated capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Lumberman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty Mite or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pug mill Op., roller, 8 tons & over, Rubber

DECISION NO. MN78-2098

POWER EQUIPMENT OPERATORS (CONT'D)

GROUP 5 (Cont'd)

tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD5 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

DECISIN NO. MN78-2098

MINN-62-TD

TRUCK DRIVERS: BUILDING, SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Sherburne County					
GROUP 1	$ 9.20	.40	.50		
GROUP 2	8.90	.40	.50		
GROUP 3	8.80	.40	.50		
GROUP 4	8.60	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bitumincus Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bitumincus Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

DECISION NO. MN78-2098

MINN-5-TD

TRUCK DRIVERS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Benton & Stearns Counties					
GROUP 1	$ 8.02	.40	.50		
GROUP 2	7.72	.40	.50		
GROUP 3	7.62	.40	.50		
GROUP 4	7.42	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Servicemen; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman. Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

STATE: Minnesota COUNTIES: *See below
DECISION NUMBER: MN78-2099 DATE: Date of Publication
Supersedeas Decision No.: MN78-2009 dated March 10, 1978 in 43 FR 10221
DESCRIPTION OF WORK: Building Construction (Including Residential Construction)

*Counties: Carlton, Cook, Itasca, Koochiching Lake and St. Louis

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ASBESTOS WORKERS	$11.10	.40	.50	1.15	
BOILERMAKERS	12.30	.85	1.00		.02
BRICKLAYERS:					
Bricklayers & Stonemasons:					
Koochiching County	11.15	.60	.30		
Cook, Lake & Carlton Counties & all that part of St. Louis County South of line between township 54 & 55 to 2 miles north of Cotton	10.27	.40	.30	.50	
Itasca County & the northern half of St. Louis County	10.875	.30			
CARPENTERS:					
Building Construction:					
Koochiching County & Cities of Ashe Lake, Crane Lake, Kabetogama & Kinmount in St. Louis County	9.45	.40			
Cook County; Cities of Alborn, Arnold, Barlett, Birch, Brookston, Canyon, Clifton, Culver, Duluth, Floodwood, Cowan, Island, Kelsey, Lakewood, Meadowlands, Munger, Palmers, Payne, Praist, Shaw Taff in St. Louis County & Southern portion of Lake County					
Carpenters, Piledrivermen & Soft Floor Layers	9.15	.40	.50	.75	
Millwrights	9.37	.40	.50	.75	
Carlton County:					
Carpenters & Piledrivermen	9.20	.40	.50	.50	
Millwrights	9.34	.40	.50	.50	
Cities of Ball Club, Bass Lake, Big Fork, Blackberry, Bovey, Bowstring, Calumet, Cohasset, Coleraine, Deer River, Dora, Lake, Dunbar, Effie, Grand Rapids, Inger Marble, Marcell, Max, Pomroy, Spring Lake, Square Lake, Scout, Taconon, Warba & Wirt in Itasca Count	9.14	.40	.50	.50	

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	Basic Hourly Rates	Fringe Benefits Payments			
		H-& W	Pensions	Vacatic	Education and/or Appr. Tr.
CARPENTERS: (Cont'd)					
Cities of Allen, Aurora, Babbit, Britt, Biwabik, Buyck, Casco, Central, Lakes, Cook, Cusson, Ely, Embarrass, Eveleth, Floreston, Forbes, Gilbert, Hoyt Lakes, Indington, Iron Junction, Makinen, McComber, Masaba, Mountain, Iron, Ridge, Sax, Sherman Corners, Sherwood, Skibo, Soudon, Tower, Virginia, Wahlstep, Winton & Zim in St. Louis & Northern portion of Lake County					
Carpenters, Soft Floor Layers, and Tile Setters	$ 9.84	.40		.30	
Cities of Goodland, Keewatin, Nashwauk, Pengilly, Sawan River, Togo & Wawina in Itasca County & Cities of Bengal, Beer Lake Buhl Chrisholm, Gheen, Gresney, Hibbing, Kelly, Lake, Nett Lake, Orr Riley, Side Lake, Silica & Tovola in St. Louis County:					
Carpenters & Soft Floor Layers	9.64	.40		.30	
Site Preparation, Excavation & Incidental Paving:					
Lake, Cook, Carlton, Itasca & St. Louis Counties	8.28	.30		.30	
Koochiching County	7.32	.30			

DECISION NO. MN78-2099

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CEMENT MASONS & PLASTERERS:					
Building Construction:					
Koochiching County:					
Cement Masons & Plasterers	$10.80	.60	.30		
Itasca Co. and the Norhtern portion of St. Louis County, North or White Face River					
Cement Masons	10.05	.30			
Plasterers	10.65	.30			
Cook, Lake, Carlton Counties & the City or Duluth in St. Louis County:					
Cement Masons	11.095	.40			
Plasterers	10.20	.30			
ELECTRICIANS:					
Cook, Lake, Carlton Counties the southerly 12 Townships of Itasca County including Harris, Feely, Blackberry, Spang, Goodland, Sago & Wawina & all of the southerly part of County bounded on the north by the lines of Kelsey Township extended east & west in St. Louis County	10.78	4%	8%	11%	1.5%
Koochiching County, Itasca County, (except that section south of a line extending east and west of the south line of Grand Rapids & Trout Lake Township), Northern part of St. Louis County bounded by the South Line of Ellsburg Township extended east and west	11.78	4%	6%	11%	1%

DECISION NO. MN78-2099

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
ELEVATOR CONSTRUCTORS:					
St. Louis & Lake Counties:					
Constructors	10.31	.75	.35	8%+a	.02
Helpers	70%JR	.75	.35	8%+a	.02
Helpers (prob.)	50%JR				
GLAZIERS:					
Cook, Lake, St. Louis, Carlton, Koochiching Counties	$ 9.60	.40	.40	b	
IRONWORKERS	11.35	.30	.55		.02
LABORERS: BUILDING CONSTRUCTION					
Carlton County					
Laborers	8.30	.30	.35	.40	
Mason Tenders: Mortar Mixers and Jackhammer Operators	8.40	.30	.35	.40	
Cook, Lake, St. Louis Co. South of T-55-N, including the City of Duluth:					
Common Laborers & Flagman	8.35	.30	.35	.40	
Mortar Mixers, Carpenters & Mason Tender, Jackhammer & Vibrator Operator	8.45	.30	.35	.40	
Itasca & Koochiching Counties and north of T-55-N, including Cities of Hibbing, Chisolm & Buhl in St. Louis County					
Common Laborer	8.80	.20	.15		
Carpenter & Mason Tender, Mortar mixer, Bricklayer Tender and Jackhammer	8.90	.20	.15		
Pipelayer (non-metallic)	9.15	.20	.15		
LATHERS:					
St. Louis & Lake Counties	11.20	.40			
MARBLE, TILE & TERRAZZO WORKERS:					
St. Louis Co. (City of Duluth)					
Marble & Tile Setter	10.43	.30			
Remainder of Counties & Remainder of St.Louis County					
Marble Setters	10.355	.555	.33		
Tile Setters	10.75	.62	.50		
Marble Finishers	9.35	.37	.50		
Tile Finishers	9.90	.62	.50		

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	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
PAINTERS:					
Brush, Tapers & Rollers	$10.81	.40	.40		.11
Spray, Structural Steel, Tapers & Paperhangers	11.41	.40	.40		.11
PLUMBERS & STEAMFITTERS:					
Koochiching County	13.90				
Cook & Carlton Counties & Southern half of St. Louis & Lake Counties	10.41	.30	.75	1.00	.05
Itasca Coutny & Northern portions of St. Louis & Lake Counties	10.65	.56	.64	1.00	.05
ROOFERS:					
Cook, Lake, Carlton Counties & Southern half of St. Louis County					
Roofers	10.58	.40	.25	1.25	
2nd Roofers	10.33	.40	.25	1.25	
Kettlemen	10.13	.40	.25	1.25	
Itasca & Koochiching Counties, the Northern half of St. Louis County					
1st Roofer	10.66	.52	.55		
2nd Roofer	10.36	.52	.55		
SHEET METAL WORKERS:					
Cook, Lake, Carlton Counties & Southern half of St. Louis County	10.81	.40	.55	1.25	.03
Itasca & Koochiching Counties, the Northern half of St. Louis County	10.92	.52	.55		
TRUCK DRIVERS:					
Building Construction:					
Koochiching County	8.80				
Itasca County	8.80				

FOOTNOTES:

a. Employer contributes 4% Basic Hourly Rate for over 5 years service, 2% of Basic Hourly Rate for 6 months to 5 years service as Vacation Pay Credit. Six (6) Paid Holidays, New Year's Day; Memorial Day; Independence Day; Labor Day; Thanksgiving Day and Christmas Day.

b. 2 weeks vacation

DECISION NO. MN78-2099

MINN-10-LAB

LABORERS: Counties of Itanka and St.Louis Counties North of T-55, Site Preparation, Excavation & Incidental Paving:	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	$ 9.08	.35	.15	.25	
CLASS II	9.18	.35	.15	.25	
CLASS III	9.33	.35	.15	.25	
CLASS IV	9.38	.35	.15	.25	
CLASS V	9.43	.35	.15	.25	
CLASS VI	9.48	.35	.15	.25	
CLASS VII	9.58	.35	.15	.25	
CLASS VIII	9.68	.35	.15	.25	

CLASS I - Unskilled-Laborers, Laborers; wrecking & demolition; Bricklayer tender, drill runner helper, Landscape gardner, Sod layer & nurseryman pipihandler (water, gas cast iron); Salamander heater & blower tender; Carpenter tender; Stonemasons tender

CLASS II - Bituminous Shoveler, Bottom man (sewer , water or gas trench), Cement handler (bulk or bag); Chain saw man, compaction equipment (hand operator); Concrete mixer operator (1 bag), Concrete Shoveler, tamper & puddler (paving)) Concrete Vibrator, Conduit layers (w/o wiring); Dumper (wagon, truck etc.), Formsetter (municipal type curb & side walk) Form setter (pavement); Jackhammer man & paving busters, Kettlemen (Bitum or lead), Mortar mixer, Power buggy, Joint drawer, tunnel laborer (at - pheric pressure)

CLASS III - Bituminous Tamper, Cofferdam work, Caisson work

CLASS IV - Drill Runner (Heavy, including churn drill)

CLASS V - Bituminous Raker, Floater, Utility Men, Pipelayers (sewer, water, gass); Deadman (Cribbing)

CLASS VII - Powderman

CLASS VIII - Tunnel Miner

DECISION NO. MN78-2099

MINN-13-LAB

LABORERS Site preparation, Excavation & Incidential Paving Koochiching County	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$ 7.70	.35	.15		
CLASS 2	7.80	.35	.15		
CLASS 3	7.85	.35	.15		
CLASS 4	7.95	.35	.15		
CLASS 5	8.05	.35	.15		
CLASS 6	8.10	.35	.15		
CLASS 7	8.15	.35	.15		
CLASS 8	8.20	.35	.15		

CLASS 1 - Skilled Laborers, Bricklayers & Carpenters Tenders; Drill Runner Helper; Laborers Wreching & Demolition, Landscape Gardner, Pipe Handler (Water, Gas, Cast Iron), Salamander Heater, & Blower Tender, Sod Layer & Nurseryman; Stonemasons tender

CLASS 2 - Bituminous Shoveler, Bottom man (Sewer, Water or gas trench), Cement Coverman (Batch Trucks); Cement handler (Bulk or bag); Chain Saw Man, Compaction equipment (hand operated), Concrete mixer (1 bag); Concrete Shoveler, Tamper & Puddler (paving), Concrete vibrator, Conduit layers (w/o wiring); Drill runner (heavy, incl. Churn Driver Dumper (wagon truck, etc.); Jackhammerman, Joint Sewer, Kettlemen (Bituminous or Lead), Mortar Mixer Paving Buster; Power Buggy; Tunnel Laborer (atmospheric pressure)

CLASS 3 - Form setters (Municipal type curb & Sidewalk) form setter(pavement)

Class 4 - Bituminous Tamper, caisson work & cofferdam

CLASS 5 - Bituminous raker, floater, & Utility man; Leadman

CLASS 6 - Nozzleman (Gunnite)

CLASS 7 - Pipelayer, (Sewer, Water & Gas)

CLASS 8 - Powderman, Tunnel Miner

DECISION NO. MN78-2099

MINN-14-LAB

LABORERS - SITE PREPARATION EXCAVATION & INCIDENTIAL PAVING Cook, Lake, Carlton & St. Louis Counties South of T-55	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS I	$ 8.48	.40	.45	.50	
CLASS II	8.58	.40	.45	.50	
CLASS III	8.73	.40	.45	.50	
CLASS IV	8.78	.40	.45	.50	
CLASS V	8.83	.40	.45	.50	
CLASS VI	8.88	.40	.45	.50	
CLASS VII	8.98	.40	.45	.50	
CLASS VIII	9.08	.40	.45	.50	

CLASS I - Unskilled Laborers, Laborers; wrecking & demolition; Bricklayer tender, drill runner helper, Landscape gardner, Sod layer & nurseryman Pipehandler (water, gas, cast iron); Salamander heater & blower tender; Carpenter tneder; Stonemasons tender

CLASS II - Bituminous Shoveler, Bottom man (sewer, water or gas trench), Cement handler (bulk or bag); Chain saw man, compaction equipment (hand operated); Concrete mixer operator (1 bag), Concrete Shoveler, tamper & puddler (paving) Concrete Vibrator, Conduit layers (w/o wiring); Dumper (wagon, truck, etc.), Formsetter (municipal type curb & side walk) Formsetter (pavement); Jackhammer man & paving busters, Kettleman (Bituminous or lead), Mortar mixer, Power buggy, Joint drawer, tunnel laborer (atmospheric pressure)

CLASS III - Bituminous Tamper, Cofferdam work, Caisson work

CLASS IV - Drill Runner (Heavy, including churn drill)

CLASS V - Bituminous Raker, Floater & Utility Man, Pipelayers (Sewer, water, gas); Leadman (Gunite)

CLASS VI - Nozzleman (Gunnite)

CLASS VII - Powderman

CLASS VIII - Tunnel Miner

DECISION NO. MN78-2099

MINN-1-PEO-1

POWER EQUIPMENT OPERATORS: Building Construction	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
CLASS 1	$14.60	.55	.50		.05
CLASS 2	12.95	.55	.50		.05
CLASS 3	12.70	.55	.50		.05
CLASS 4	12.10	.55	.50		.05
CLASS 5	11.75	.55	.50		.05
CLASS 6	11.65	.55	.50		.05
CLASS 7	11.40	.55	.50		.05
CLASS 8	11.28	.55	.50		.05
CLASS 9	11.20	.55	.50		.05
CLASS 10	10.93	.55	.50		.05
CLASS 11	10.45	.55	.50		.05

CLASS 1 - Helicopter Operators
CLASS 2 - Truck & crawler Cranes with 300' of Boom & over including Jib
CLASS 3 - Truck & crawler Cranes with 200' of Boom up to & not including 200' of Boom including jib.
CLASS 4 - Truck
CLASS 5 - Master Mechanic
CLASS 6 - Derrick (Guy & Stiff Leg); Hoist engineer (3 drums or more); Locomotive Operator; Overhead Crane Operator, (Inside Building Perimeter); Truck & Crawler Cranes up to 150' of Boom including jib.
CLASS 7 - Air compressor Operator; Pump & or Conveyor; 2 or more Mechanics; Hoist engineer (2 drum); Mechanic or welder; Pumperete or Complaco type Machine Operator; Fork Lift Operator
CLASS 8 - Boom truck Operator; concrete Mixer Operator; Drill Rigs (Heavy Duty Rotary or Churn Drill when used for caisson drilling or when drilling for elevator cylinder or Building Construction; Front End Loader Opr., Hoist Engineer (1 drum); Power Plant Engineer (100 KW & over); Straddle carrier Operator; Tractor Operator (over D-2); Well Point Pump Operator
CLASS 9 - Concrete Batch Plant Operator; gunnite Operator; Tractor Operator (D-2 or similar size 7 Front End Loader Operator-up to ½ cu. yd.)
CLASS 10 - Air Compressor Operator; Pump & or Conveyor Operator; Fireman-Temporary Heat; Brakeman; Pick Up Sweeper (combustion engine operated); Truck Crane Oiler
CLASS 11 - Mechanic Space Heater (Temporary Heat) Oiler or Greaser

DECISION NO. MN78-2099

MINN-7M-PEO-2-3

SITE PREPARATION, EXCAVATION & RESIDENTIAL PAVING POWER EQUIPMENT OPERATORS; Cook, Lake, & St. Louis Counties	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.75	.55	.50		.05
GROUP 2	11.46	.55	.50		.05
GROUP 3	11.35	.55	.50		.05
GROUP 4	11.02	.55	.50		.05
GROUP 5	10.93	.55	.50		.05
GROUP 6	10.55	.55	.50		.05
GROUP 7	10.05	.55	.50		.05

GROUP 1 - Helicopter Pilot
GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity
GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conmy or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over
GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 22 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer
GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill. Engineer in charge of Plant requiring First Class License, fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Lamplighter, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamper machines Op., (power-driven - Mighty Might or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning

POWER EQUIPMENT OPERATORS (Cont'd)

or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & hallast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman & Car Heater op., Gravel screening plant op., greaser leverman, mec helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

SITE PREPARATION, EXCAVATION INCIDENTIAL PAVING

(JURISDICTION - NEXT PAGE)

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.45	.55	.50		.05
GROUP 2	11.16	.55	.50		.05
GROUP 3	10.85	.55	.50		.05
GROUP 4	10.73	.55	.50		.05
GROUP 5	10.63	.55	.50		.05
GROUP 6	9.85	.55	.50		.05
GROUP 7	9.45	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Road Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conwy or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Lamberman, Locomotive, all types, Mechanic or welder, Multiple machines such as air compressors, welding machines, generators, pumps or [illegible] boilers, paving breaker or tamping machines op., (power-driven - Mucking Machine or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper Capacity, Pipeline wrapping, cleaning

POWER EQUIPMENT OPERATORS (Cont'D) SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING-CARLTON CO; KOOCHICHING CO., EAST OF A NORTH SOUTH LINE FROM THE CANADIAN BORDER TO PELLAND TO BIG FALLS & MINN. HWY. #6; ITASCA COUNTY EAST OF THE WESTERN RIGHT OF WAY OF MINN. HWY. #6.

or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & hallast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trenching machine Op., (sewer, water, gas) turnapull op.,(or similar type) well point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip Spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman,conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

MINN-7-PEO

POWER EQUIPMENT OPERATORS: SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING Remainder of Itasca Koochiching	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	$14.00	.55	.50		.05
GROUP 2	9.82	.55	.50		.05
GROUP 3	9.32	.55	.50		.05
GROUP 4	9.18	.55	.50		.05
GROUP 5	9.10	.55	.50		.05
GROUP 6	8.57	.55	.50		.05
GROUP 7	8.17	.55	.50		.05

GROUP 1 - Helicopter Pilot

GROUP 2 - Crane with over 135' Boom, excluding jib, Dragline and/or other similar equipment w/shovel type controls 3 cu. yds. & over Mfg. rates capacity

GROUP 3 - Cableway Op., concrete Mixer, Stationary Plant over 34E, Derrick, Dragline and/or similar equipment with shovel type control up to 3 cu. yds. Mfg. rates capacity, Dredge Operator or Engineer, dredge Oper. (power) & Yds. & over, Grader or Motor Patrol Finishing earth & bituminous, Locomotive crane Operator, Master Mechanic, Mixer (paving) Concrete Paving Op., Mead Mole., Op., incl. power supply, Mucking Mach., incl. mucking operations Conway or similar type, Refrigeration Plant Engineer, Tandem Scraper, Tractor Op. (Boom Type), Truck Crane Op., Tugboat Op. 100 HP & over

GROUP 4 - Dual Tractor Op., Elevating Grader Op., Pumpcrete Op., Scraper Op., Struck Capacity 32 cu. yds. & over, Self-Propelled. Traveling Soil Stabilizer

GROUP 5 - Air track Rock Drill, Asphalt Bituminous Stabilizer Plant Op., Crushing Plant Op., or Gravel Washing, Crushing and Screening Plant Op., Dope Machine Op., Drill Rigs, Heavy Rotary or Churn or Cable Drill, Engineer in charge of Plant requiring First Class License, fork Lift or Lumber Stacker, Front End Loader Op., Loader Op., over 1 cu. yds., Hoist Engineer, Hydraulic Tree Planter, Launchman, Locomotive, all types, Mechanic or welder, Multiple machines, such as air compressors, welding machines, generators, pumps or crane oilers, paving breaker or tamping machines op., (power-driven - Mighty Might or similar type, Pick-up sweeper, 1 cu. yd. & over Hopper capacity, Pipeline wrapping, cleaning

(POWER EQUIPMENT OPERATORS (Cont'd)

or bending machine Op. Power Plant Engineer, Power actuated horizontal boring mach., over 6" op., pugmill op., roller, 8 tons & over, Rubber tired farm tractor, backhoe att., sheep foot op., tie tamper & ballast mach. Op., Tractor op., over D2, TD6 or similar HP with power take-off, tractor Op., over 50 HP without power take-off, trench machine Op., (sewer, water, gas) turnapull op., (or similar type) point installation, dismatling or repair mechanic

GROUP 6 - Air compressor Op. 375 CFR or over, bituminous spreader and bituminous finishing machine op., Concrete dist. & Spreader op., finishing machine longitudinal float op., joint mach. op., spray., concrete mixer op. 14S and under, concrete op. (Mult. Blade), curb mach. op., Fine grade Op., form trench digger, front end loader op. (up to & incl. 1 cu. yd.), grader op. (motar patrol), gunite op. gunall, lead greader on truck or rack, loader op., power actuated Augars and boring mach. op. power actuated jacks op., pump op., roller op., self-propelled chip spreader, shouldering mach. Op., stump chipper op., tractor op. (D2, TD6 or similar HP with power take-off)

GROUP 7 - Brakeman, switchman, conveyor op., deckhand, Fireman, Tank Car Heater op., Gravel screening plant op., greaser leverman, mech. helper, mech. space heater, oiler, self-prop. vib. packer op., sheep foot roller, tractor op. 50 HP or less w/o power take-off, truck crane oiler

MINN-62-TD

TRUCK DRIVERS: BUILDING, SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING

Cook, Lake, Carlton & St. Louis Counties

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
GROUP 1	9.20	.40	.50		
GROUP 2	8.90	.40	.50		
GROUP 3	8.80	.40	.50		
GROUP 4	8.60	.40	.50		

GROUP 1 - Driver (Hauling machinery for employer's own use, including operation of hand & power operated winches); Truck train Mechanic, Welder; Tractor-Trailer; Off-Road Truck

GROUP 2 - Tri-axle (including 4-Axles); Dump Dry Batch Hauler; Tank Truck (Gas, Oil, Road Oil & Water); Boom & "A" Frame; Ready Mix Concrete; Slurry Driver.

GROUP 3 - Bituminous Distributor; Bituminous Distributor (1-Man Operation); Tandem Axle.

GROUP 4 - Bituminous Distributor Spray (rear-end oiler); Dumpman; Greaser & truck Serviceman; Tank Truck Helper (Gas, Oil, Road Oil & Water) Teamster and Stableman, Tractor Operator (Wheel Type used for any purpose) Pilot car driver, self-Propelled Packer; Slurry Operator; Single Axle Trucks.

MINN-5-TD

DECISION NO. MN78-2099	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
TRUCK DRIVERS:					
SITE PREPARATION, EXCAVATION & INCIDENTIAL PAVING					
ITASCA & KOOCHICHING COS.					
GROUP 1	$ 8.02	.40	.50		
GROUP 2	7.72	.40	.50		
GROUP 3	7.62	.40	.50		
GROUP 4	7.42	.40	.50		

GROUP 1
Driver (hauling machinery for employer's own use including operation of hand & power operated winches); Truck train mechanic; Welder; Tractor-Trailer; Off road truck.

GROUP 2
Tri-Axle (including 4 Axles); Dump dry batch hauler; Tank truck (gas, oil, road oil & water); Boom & "A" Frame; Ready mix concrete; Slurry driver.

GROUP 3
Bituminous distributor driver; Bituminous distributor (1 man operation); Tandem axle.

GROUP 4
Bituminous distributor spray (rear-end oiler); Dumpman; Greaser & truck service man; Tank truck helper (gas, oil, road oil & water); Tamper and stableman; Tractor operator (wheel type used for any purpose); Pilot car; Self-propelled packer; Slurry operator; Single axle.

SUPERSEDEAS DECISION

STATE: North Carolina COUNTIES: Forsyth, Stokes, Surry & Yadkin

DECISION NUMBER: NC78-1081 DATE: Date of Publication

Supersedes Decision No. NC77-1017 dated February 11, 1977 in 42 FR 8979

DESCRIPTION OF WORK: Residential construction consisting of single family homes and garden type apartments up to and including 4 stories.

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BRICKLAYERS	$6.00				
CARPENTERS	4.75				
CEMENT MASONS	5.00				
ELECTRICIANS	5.00				
LABORERS:					
Unskilled	3.30				
Mason tenders	3.50				
Pipelayers	3.97				
PAINTERS, Brush	5.00				
PLASTERERS	5.75				
PLUMBERS & PIPEFITTERS	5.49				
ROOFERS	6.00				
SHEET METAL WORKERS	4.62				
SOFT FLOOR LAYERS	4.29				
TILE SETTERS	4.50				
TRUCK DRIVERS	3.30				
Welders - Rate for craft.					
POWER EQUIPMENT OPERATORS:					
Asphalt paver	4.45				
Asphalt raker	3.85				
Backhoe	4.83				
Forklift	4.07				
Loader	4.25				
Motor grader	5.14				
Roller	3.51				
Tractor	4.50				

SUPERSEDEAS DECISION

STATE: Pennsylvania COUNTY: Lebanon
DECISION NO.: PA78-3068 DATE: Date of Publication
Supersedes Decision No. PA77-3121 dated September 9, 1977 in 42 FR 45612.
DESCRIPTION OF WORK: Building Erection and Foundation Excavation, (does not include single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos Workers	$10.76	.67	.90		.01
Boilermakers	13.775	1.075	1.00		.02
Bricklayers	10.07	.60	.57		.02
Carpenters	10.30	.40	.50		.03
Cement Masons:					
West of Rte. 501	10.465	.65	.50		
East of Rte. 501	9.64		1.05		
Electricians:					
Lawn, East Hanover & Indiantown Gap Military Reservation	10.86	.65	3%+.49		½ of 1%
Portion of Lebanon County which extends South and East of Interstate Route 81	9.59	.65	3%+.49		½ of 1%
Remainder of County	9.40	.65	3%		½ of 1%
Elevator Constructors	10.55	.745	.56	b+c	.02
Elevator Constructors' Helpers	7.385	.745	.56	b+c	.02
Elevator Constructors' Helpers (Prob.)	5.275				
Glaziers:					
Twps. of Bethel, Jackson, Mill Creek, Lebanon., E. of Rte. 72, Heidlberg & Richland	9.19	.40	.40		.01
Remainder of County	9.39	.40	.40		.01
Ironworkers	11.28	.84	1.36		.03
General Laborers	6.85	.45	.35		
Operator of jackhammer, paving breaking and other pneumatic, electrical and mechanical tools, laying of all clay, terra cotta, ironstone vitrified concrete or non-metallic pipe and the making of joints for same, wagon drill operator, cofferdam (below 10'), tunnel free air, handling and using cutting or burning torches in the wrecking of buildings, blasters, plasterer tenders, mason tenders, scaffold builders and removal of power buggies	6.95	.45	.35		

DECISION NO. PA78-3068

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Lathers	9.83		.15		.01
Lead Burners	10.75	.40	.25	a	.01
Line Construction:					
Linemen & cable splicers	11.39	.45	3%		3/8%
Groundmen	6.83	.45	3%		3/8%
Winch truck operator	7.97	.45	3%		3/8%
Marble Setters	9.60	.60	.48		
Millwrights	11.45	.50	.55		.05
Painters (East of Route 72)					
Brush	9.35	.70	.65		
Structural steel & spray	10.40	.70	.65		
Highway bridges	10.80	.70	.65		
Painters (West of Route 72)					
Brush	9.05	.29	.27		.02
Structural steel	9.50	.29	.27		.02
Spray	9.80	.29	.27		.02
Piledrivermen	11.12	2.33	1.35	g	.12
Plasterers:					
East of Rte. 501	9.66		1.05		.01
West of Rte. 501	9.60	.65	.50		.01
Plumbers & steamfitters:					
East of Rte. 501	12.26	.80	1.45		.11
West of Rte. 501	11.30	.70	.80		.12
Roofers:					
Annville, Cold Springs, East Hanover, North Annville, North Cornwall, North Londonderry, South Annville, South Londonderry, Union, West Cornwall Twps.:					
Compositions	10.41	.80	.55		
Remainder of County:					
Composition, damp & Waterproofing	10.89	.95		f	
Sheet Metal Workers	10.05	1.39	1.18		.05
Soft Floor Layers	9.20	.50	.55		.05
Sprinkler Fitters	12.31	.75	1.05		.08
Stonemasons	10.07	.60	.57		.02
Terrazzo Workers	9.03	.60			
Tile Setters	9.03	.60			

DECISION NO. PA78-3068

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Truck Drivers:					
Pick-ups, dump, flat trucks to & including 2 highway license plates	8.39	d	e		
Transit-mix, winch, trucks, tractor trailers, all types euclids, ross lumber carriers & trucks over 2 plates	8.64	d	e		

Welders - rate for craft

PAID HOLIDAYS:

A-New Year's Day; B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. 8 paid holidays, A through F and Washington's Birthday, Good Friday and Christmas Eve, provided the employee has worked 45 full days for the employer during the 120 days prior to the holiday and is available for work the days preceding and following the holiday.

b. Employer contributes 4% basic hourlyrate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

c. Six paid holidays: A through F, plus the Friday after Thanksgiving Day.

d. $71.37 per month for employees who have worked sixty hours or more during the month.

e. $46.80 per month for employees who have worked sixty hours or more during the month.

f. Paid holidays: Election Day and Labor Day, July 4th.

g. Paid Holidays: Washington's Birthday; Good Friday; Memorial Day; Labor Day; Presidential Election Day; Veterans Day; Thanksgiving Day and Christmas Day.

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr.
GROUP 1	$12.44	7%	10.3%	a	1.8%
GROUP 2	12.15	7%	10.3%	a	1.8%
GROUP 3	11.28	7%	10.3%	a	1.8%
GROUP 4	10.51	7%	10.3%	a	1.8%
GROUP 5	10.04	7%	10.3%	a	1.8%
GROUP 6	9.13	7%	10.3%	a	1.8%
GROUP 7	12.69	7%	10.3%	a	1.8%
GROUP 7-A	12.94	7%	10.3%	a	1.8%
GROUP 7-B	13.18	7%	10.3%	a	1.8%

GROUP 1: Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above

GROUP 2: All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above

GROUP 3: Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above

GROUP 4: Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seaman pulverizing mixer, power brooms, seeding spreader, fireman (for power equipment), machines similar to above

GROUP 5: Fireman, grease truck

GROUP 6: Oilers and deck hands (pneumatic boats), core drill helper

GROUP 7: All machines with booms (including jib, masts, loads, etc.): 100 ft. and over

GROUP 7-A: 150 ft. and over

GROUP 7-B: 200 ft. and over

FOOTNOTE:
a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day, provided the employee works the day before and after the holiday.

SUPERSEDEAS DECISION

STATE: Pennsylvania COUNTY: Lancaster
DECISION NO.: PA78-3070 DATE: Date of Publication
Supersedes Decison No. PA77-3104 dated July 22, 1977, in 42 FR 37762.
DESCRIPTION OF WORK: Building Erection and Foundation Excavation, (does not include single family homes and garden type apartments up to and including 4 stories).

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Asbestos workers	$10.76	.67	.90		.01
Boilermakers	13.775	1.075	1.00		.02
Bricklayers	9.80	.45	.45		
Carpenters	10.30	.50	.55		.05
Cement masons	9.94	.35	.25		.01
ELectricians:					
W. Calico, E. Calico, Brecknock, E. Carl, & Caernarvon Twps.	11.69	.78	3% + .20		.03
That portion nothwest of a line extending from the Susquehanna River to the intersection of State Highways 441 and 241 along 241 to the Borough of Elizabethtown around the limits of Elizabethtown on the west and north side, but including the Masonic Homes in Elizabethtown, continuing along State Highway 241 to Lebanon County and that portion north of the Pennsylvania Turnpike, but including all building on the Turnpike, from Lebanon County line West Cocalico township.	9.59	.65	3% + .49		½ of 1%
Remainder of County	10.10	.45	3%		1/8 of 1%
Elevator Constructors	10.55	.745	.56	a+b	.025
Elevator Constructors' Helpers	70%ofJF	.745	.56	a+b	.025
Elevator Constructors' Helper (Prob.)	50%ofJF				
Glaziers	8.85	.40	.30		.01
Ironworkers	11.28	.84	1.36		.03
Laborers:					
General Laborers	6.85	.65	.57		
Operators of Jackhammer	7.05	.65	.57		
Wagon drill	7.15	.65	.57		
Handling of all materials	7.00	.65	.57		
Laborers assisting tile	6.90	.65	.57		
Handling & using dynamite	7.10	.65	.57		
Caisson Work (Top Men)	7.10	.65	.57		
Caisson Work (Bottom Men)	7.30	.65	.57		
Mixer Man	7.25	.65	.57		
Lathers	10.11	.40	.25		.01
Lead Burners	10.75	.40	.25	c	.01

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
Line Construction:					
Linemen	11.39	.45	3%		3/8 of 1%
Cable splicers	11.39	.45	3%		3/8 of 1%
Groundman	6.83	.45	3%		3/8 of 1%
Winch truck operators	7.97	.45	3%		3/8 of 1%
Marble setters	8.55	.45	.45		
Millwrights	11.45	.50	.55		.05
Painters:					
Elizabeth Dowetal Township					
Brush	9.05	.29	.27		.02
Steel	9.50	.29	.27		.02
Spray	9.80	.29	.27		.02
Remainder of County:					
Brush	9.35	.70	.65		
Steel	10.40	.70	.65		
Spray	10.40	.70	.65		
Roller	9.35	.70	.65		
Piledriverman	11.12	2.33	1.35	e	.12
Plasterers	8.60	.35	.25		.01
Plumbers	11.30	.70	.80		.12
Roofers:					
Composition, damp & waterproofing	10.80	.95		d	
Slate, tile & asbestos	11.25	.95		d	
Roofers, precast slab	11.60	.95		d	
Sheet metal workers	10.05	1.39	1.18		.05
Sprinkler fitters	12.31	.75	1.05		.08
Soft floor layers	9.20	.50	.55		.05
Steamfitters	11.30	.70	.80		.12
Stonemasons	9.80	.45	.45		
Terrazzo workers	8.55	.45	.45		
Tile setters	8.55	.45	.45		
Welders - Receive rate prescribed for craft performing operation to which welding is incidental.					

PAID HOLIDAYS:
A-New Year's Day' B-Memorial Day; C-Independence Day; D-Labor Day; E-Thanksgiving Day; F-Christmas Day.

FOOTNOTES:

a. Employer contributes 8% basic hourly rate for 5 years or more of service or 6% basic hourly rate for 6 months to 5 years of service as Vacation Pay Credit.

b. Six (6) paid holidays: A through F, plus the Friday after Thanksgiving Day.

c. Nine paid Holidays: A through F and Washington's Birthday, Good Friday and Christmas Eve provided the employee has worked 45 full days for the employer during the 120 days prior to the holiday and is available for work the days preceeding and following the holidays.

d. Paid Holidays: Independence Day, Election Day and 4th of July.

e. Paid Holiday: Washington's Birthday; Good Friday; Memorial Day; Labor Day; Presidential Election Day; Veterans Day and Thanksgiving Day.

POWER EQUIPMENT OPERATORS	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	App. Tr
GROUP 1	$12.44	7%	10.3%	a	1.8%
GROUP 2	12.15	7%	10.3%	a	1.8%
GROUP 3	11.28	7%	10.3%	a	1.8%
GROUP 4	10.51	7%	10.3%	a	1.8%
GROUP 5	10.04	7%	10.3%	a	1.8%
GROUP 6	9.13	7%	10.3%	a	1.8%
GROUP 7	12.69	7%	10.3%	a	1.8%
GROUP 7-A	12,94	7%	10.3%	a	1.8%
GROUP 7-B	13.18	7%	10.3%	a	1.8%

GROUP 1: Machines doing hook work, any machine handling machinery, cable spinning machines, helicopters, machines similar to the above

GROUP 2: All types of cranes, all types of backhoes, cableways, draglines, keystones, all types of shovels, derricks, trench shovels, trenching machines, hoist with two towers, pavers 21E and over, all types overhead cranes, building hoists (double drum) gradalls, mucking machines in tunnel, all front end loaders 3-½ c.y. and over, tandem scrapers, pippin type backhoes, boat Captains, batch plant operators (concrete) drills, self-contained rotary drills, fork lifts, 20 ft. lift and over machine to the above

GROUP 3: Conveyors, building hoists (single drum) scrapers and tournapulls, spreaders, high or low pressure boilers, concrete pumps, well drillers, bulldozers and tractors, asphalt plant engineers, roller (high grade finishing), ditch witch type trencher, all loaders under 3-½ cu. yds., mechanic-welders, motor patrols, drill helper-self contained rotary drills, core drill operator, forklift trucks under 20 ft. lift, machines similar to the above

GROUP 4: Welding machines, well points, compressors, pumps, heaters, farm tractors, form line graders, fine grade machines, road finishing machines, concrete breaking machines, rollers, seeman pulverizing mixer, power broom, seeding spreader, tireman (for power equipment), machines similar to above

GROUP 5: Fireman, grease truck

GROUP 6: Oilers and deck hands (personnel boats), core drill helper

GROUP 7: All machines with booms (including jib, masts, loads, etc.): 100 ft. and over

GROUP 7-A: 150 ft. and over

GROUP 7-B: 200 ft. and over

FOOTNOTES:
a. Paid Holidays: New Year's Day, Memorial Day, Independence Day, Labor Day, Thanksgiving Day, and Christmas Day, provided the employee works the day before and after the holiday.

SUPERSEDEAS DECISION

STATE: South Carolina COUNTY: Statewide
DECISION NUMBER: SC78-1085 DATE: Date of Publication
Supersedes Decision No. SC75-1079 dated September 5, 1975 in 40 FR 41380
DESCRIPTION OF WORK: Water and Sewer Construction; and Heavy Construction

	Basic Hourly Rates	Fringe Benefits Payments			
		H & W	Pensions	Vacation	Education and/or Appr. Tr.
BOILERMAKERS	$9.95	1.05	1.05		.02
BRICKLAYERS/MANHOLE BUILDERS	3.92				
CARPENTERS	5.32				
CEMENT MASONS	4.67				
ELECTRICIANS	6.87				
IRONWORKERS, Reinforcing	6.50				
LABORERS:					
Unskilled	3.17				
Air tool operators	3.50				
Asphalt sweepers	3.60				
Pipelayers	3.71				
PILEDRIVERS	7.00				
PLUMBERS; PIPEFITTERS	7.98				
POWER EQUIPMENT OPERATORS:					
Bulldozer	4.50				
Backhoe operators	4.70				
Chain saw operators	4.00				
Cranes	5.81				
Draglines	5.29				
Equipment mechanics	5.22				
Front end loaders	3.99				
Motor graders	4.25				
Roller operators	3.25				
Scrapers - Pans	4.11				
Tractors	3.46				
Trenching machines	3.92				
TRUCK DRIVERS	3.34				
WELDERS	6.00				

[FR Doc. 78-27106 Filed 9-28-78; 8:45 am]

federal register

FRIDAY, SEPTEMBER 29, 1978
PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Institute of Museum Services

■

MUSEUM SERVICES PROGRAM

Eligibility Conditions, Funding Requirements and Criteria and Administration

[4110-24]

Title 45—Public Welfare

SUBTITLE A—DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, GENERAL ADMINISTRATION

PART 64—MUSEUM SERVICES PROGRAM

Final Rules

AGENCY: Institute of Museum Services, HEW.

ACTION: Final rules.

SUMMARY: These rules govern the program, administered by the Institute of Museum Services, to provide Federal financial assistance to museums. The rule implements the Museum Services Act. It states eligibility conditions, funding requirements and criteria and other rules for the administration of the program.

EFFECTIVE DATE: These rules are effective September 29, 1978.

FOR FURTHER INFORMATION CONTACT:

Ms. Peggy Loar, 202-245-6753.

SUPPLEMENTARY INFORMATION:

1. *Nature of program.* The Museum Services Act ("the Act"), which is title II of the Arts, Humanities and Cultural Affairs Act of 1976, was enacted on October 8, 1976.

The purpose of the Act is stated in section 202 as follows:

> It is the purpose of this title to encourage and assist museums in their educational role, in conjunction with formal systems of elementary, secondary, and postsecondary education and with programs of nonformal education for all age groups; to assist museums in modernizing their methods and facilities so that they may be better able to conserve our cultural, historic, and scientific heritage; and to ease the financial burden borne by museums as a result of their increasing use by the public.

The Act establishes an Institute of Museum Services (IMS) consisting of a National Museum Services Board and a Director.

The National Museum Services Board consists of 15 members appointed for fixed terms by the President with the advice and consent of the Senate. The Chairman of the Board is designated by the President from the appointed members. Members are broadly representative of various museums and curatorial, educational, and cultural resources of the United States. In addition to the members appointed by the President, the following serve as members of the Board: The Chairman of the National Endowment for the Arts, the Chairman of the National Endowment for the Humanities, the Secretary of the Smithsonian Institution, the Director of the National Science Foundation, and the U.S. Commissioner of Education. The Board has the responsibility for establishing the general policies of the Institute.

The Director of the Institute is appointed by the President, with the advice and consent of the Senate. The Director has responsibility for the general administration of the Institute and is authorized, subject to the policy direction of the Board, to make grants to museums under the Act.

IMS is an agency within the Department of Health, Education, and Welfare.

The Act lists a number of illustrative activities for which grants may be made, including assisting museums to meet their administrative costs for preserving and maintaining their collections, exhibiting them to the public, and providing educational programs to the public. Other activities are designed to aid museums in installing displays, interpretations and exhibitions; developing and maintaining professionally trained staff; developing or demonstrating new methods of conservation; carrying out specialized museum programs for specific segments of the public, and engaging in activities in cooperation with other museums.

For the Federal fiscal year ending September 30, 1978, $3.7 million has been appropriated for grants under the Act.

2. *Need for regulations.* Certain rules are needed for the proper administration of a Federal grant program. These rules relate to such matters as the types of institutions eligible to apply for a grant, the types of assistance available, the requirements which applicants must meet, and the criteria used to judge applications. Applicants must know this information to determine whether to apply and how to submit applications. Federal law requires publication of these rules in the FEDERAL REGISTER (5 U.S.C. 552). These rules generally appear in the form of program regulations.

Under the applicable procedures of this Department, the public is invited to participate in the development of program regulations through the methods set forth in Section 553, Title 5, United States Code. After public comments on proposed regulations have been received and considered, final regulations are published in the FEDERAL REGISTER together with an explanation of the agency's response to the comments. These regulations are codified in the Code of Federal Regulations (CFR), the official compilation of Federal regulations. The Institute of Museum Services has followed these procedures with respect to the Museum Services program.

The document set forth below contains the Institute's final regulations for that program.

3. *Steps in development of the regulations: Public comment.* On January 27, 1977, a notice of intent to issue regulations for the Museum Services program was published in the FEDERAL REGISTER. The notice alerted the public to the passage of the Act and the intention of the Department of Health, Education, and Welfare to issue program regulations under it. The notice invited public comment on specific issues.

The National Museum Services Board was sworn in on December 16, 1977, and promptly took up rulemaking procedures at its meeting of December 17, 1977. Steps were taken to develop proposed regulations. At meetings held on January 6 and 7, and February 12 and 13, 1978, the Board extensively considered and discussed the proposed regulations and adopted them at its meeting of February 13 for publication in the FEDERAL REGISTER.

The proposed regulations were published in the FEDERAL REGISTER on March 28, 1978, at 43 FR 13012. (A summary of the proposed regulations was included in the March 28 publication and is not repeated here.) Comments received in response to the January 27, 1977 notice of intent and responses to these comments were summarized in an appendix to the proposed regulations also published in the FEDERAL REGISTER.

The public was invited to submit comments on the proposed regulations. Over 20 letters with comments were received from museums, other interested agencies and organizations, and members of the public. These comments have been considered in the development of the final regulations. Significant public comments and the Institute's response are summarized in appendix B to this document.

In general, commenters supported the approach in the proposed regulations but offered suggestions as to the handling of particular problems. Commenter interest was high in the sections dealing with definition of museum, eligibility, types of assistance available, and funding criteria.

On July 30 and 31, the National Museum Services Board considered and approved the publication of the final regulations, but directed that further public comment be invited on certain sections. See item 5 below.

The final regulations govern the program for fiscal year 1978 and for future fiscal years until amended.

4 *Summary of major changes.* The following paragraphs summarize major changes made in the final regulations as compared with the proposed regulations. These changes were made in response to public comment or as a

result of further consideration by the Institute. Since applications for the current fiscal year were prepared in light of the proposed rules, certain changes are made applicable only to competitions for future fiscal years.

Exhibition facilities. The final regulations clarify the status of institutions which have all the attributes of a museum except that they lack exhibition facilities. An institution which owns and cares for objects but lacks facilities for their exhibition is a "museum," for purposes of the program, if the institution exhibits the objects through other facilities. However, in view of its generally lower operating expenses, such an institution receives lower priority in competition for operating grants than institutions with exhibition facilities. (§§ 64.3(e); 64.12(c))

Joint applictions. The final regulations make clear that two or more museums may submit a joint application for a grant under the Act. (§ 64.6)

Preservation of structures. The final regulations indicate that assistance may be made available for the preservation of museum structures, as well as the modernization of facilities. However, in view of limited funds, the regulations preclude such assistance for fiscal years 1978 or 1979. (§ 64.8(a)(7))

Criteria; diversity in selection of applicants. To achieve diversity in the distribution of assistance under the Act, the regulations authorize the Institute, in selecting grantees, to consider the location, size, and category of applicants seeking assistance. On the basis of these factors, the Institute may make appropriate adjustments in the ranking of applications to secure diversity. (§ 64.12(d))

Evaluation criteria. Evaluation criteria applicable to the review and evaluation of grant applications submitted in fiscal year 1978 are not substantially changed. These criteria are set forth in appendix A. Since they pertain only to fiscal year 1978, they will not be codified in the Code of Federal Regulations. The criteria for evaluation of applications submitted in fiscal year 1979 and succeeding fiscal years are reorganized, rewritten, and simplified in response to public comment and to the experience of the Institute in reviewing applications submitted in the current fiscal year. The criteria for fiscal year 1979 and succeeding fiscal years are in §§ 64.13 and 64.14. Further public comment is invited on the criteria in §§ 64.13 and 64.14. These sections provide separate sets of criteria for operational and project support. Certain criteria which proved difficult to apply have been eliminated.

An applicant for operational assistance is to be evaluated on the basis of its total operation especially as it would be if the application for general operational support is granted. Emphasis is placed on quality of museum services, quality of collections and exhibits; accessibility of services and collections and exhibits; population served; quality of financial management and of long range plans for financial and program development; and community commitment. Prior use of IMS funds is also considered where applicable. (§ 64.13)

Since assessment by readers and reviewers is primarily based on material submitted in the application, applicants must submit complete and informative applications responding to all criteria. (§§ 64.13 and 64.14)

Reports. A new section (§ 64.19) has been added to clarify the duty of a grantee to submit a final report describing the extent to which grant performance carried out the objectives stated in the grantee's application and reflects the applicable evaluation criteria.

Other changes. The status of historic building museums is clarified (§ 64.3). In the interest of simplifying the regulations, § 64.11 relating to applications is limited to basic requirements for program participation. Provisions concerning the content of applications will appear in IMS' annual program announcement stating the date for receipt of applications.

Other technical and typographical changes are made.

5. *Further public comment.* The proposed regulations invited the public to comment on the funding criteria for the program. In the final regulations, the funding criteria for fiscal year 1979 and succeeding years, particularly the criteria for general operational support, have been substantially revised and simplified. A number of suggestions made by public commenters are reflected in these changed criteria. However, changes in the criteria also respond to views expressed by persons who were selected to read applications submitted in the fiscal year 1978 cycle as well as a general reconsideration by the National Museum Services Board. Under these circumstances, in the interest of full public participation, the Institute believes that an additional opportunity for public comment for the criteria in §§ 64.13 and 64.14 is warranted before these criteria are used. Accordingly, members of the public are particularly invited to comment on these sections. Comments must be received on or before (insert 30th day after publication). Comments should be addressed to: Mrs. Lee Kimche, Director, Institute of Museum Services, Hubert Humphrey Building, Room 326-H, 200 Independence Avenue SW., Washington, D.C. 20201.

A program announcement for fiscal year 1979 will not be issued until IMS has had an opportunity to review these comments and to make further changes in the criteria if warranted.

After consideration of all substantive comments, title 45 of the Code of Federal Regulations is amended by adding a new part 64, to read as follows and the criteria set forth in appendix A are adopted.

(Catalog of Federal Domestic Assistance No. 13.923, Museum Services Program.)

Dated: August 30, 1978.

GEORGE C. SEYBOLT,
Chairman, National Musuem Services Board.
LEE KIMCHE,
Director, Institute of Museum Services.

Approved: September 25, 1978.

HALE CHAMPION,
Acting Secretary of Health, Education, and Welfare.

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AUTHORITY: Secs. 201-210, Pub. L. 94-462 (20 U.S.C. 961-68)

§ 64.1 Purpose of museum services program.

The purpose of this program of Federal financial assistance is to ease the financial burden borne by museums as a result of their increasing use by the public and to encourage and assist them to carry out their educational and conservation roles as well as other functions and to modernize their methods and facilities.

§ 64.2 Scope of this document.

This document sets forth rules for the award of grants to museums from funds appropriated under the Museum Services Act including rules governing the eligibility of applicant institutions, the type of assistance which may be provided, requirements which appli-

cants must meet and criteria to be used in judging applications.

§ 64.3 Definition of museum.

(a) As used in this document, "museum" means a public or private nonprofit institution which is organized on a permanent basis for essentially educational or aesthetic purposes and which, using a professional staff:

(1) Owns or uses tangible objects, whether animate or inanimate;

(2) Cares for these objects; and

(3) Exhibits them to the public on a regular basis.

(b) As used in this document, the term "museum" includes (but is not limited to) the following institutions if they satisfy the provisions of this section:

(1) Aquariums and zoological parks;

(2) Botanical gardens and arboreta;

(3) Museums relating to art, history (including historic building museums), natural history, science and technology; and

(4) Planeteriums.

(c) For the purposes of this section, an institution uses a professional staff if it employs at least one staff member, whether paid or unpaid, who devotes his or her time primarily to the acquisition, care, or exhibition to the public of objects owned or used by the institution. The Institute encourages museums to use paid professional staff.

(d) An institution does not exhibit objects to the public for the purposes of this section if the display or use of the objects is incidental to an overall purpose of the institution which is other than their exhibition to the public.

(e) An institution which exhibits objects it owns through other facilities exhibits objects to the public for the purposes of this section. See § 64.12(c).

§ 64.4 Other definitions.

The following other definitions apply in this document:

"Act" means the Museum Services Act, Title II of the Arts, Humanities and Cultural Affairs Act of 1976, Pub. L. 94-462 (20 U.S.C. 961-968).

"Applicant" means an institution which is eligible and applies for assistance under the Act and this document.

"Board" means the National Museum Services Board established under section 204 of the Act.

"Collection" includes objects owned, used or loaned by a museum as well as literary, archival and documentary resources required for the study and interpretation of these objects.

"Conservation" includes, but is not limited to, the following functions, as applied to animate as well as inanimate objects: Technical examination of materials, techniques, and conditions; provision, insofar as practicable, of optimum environmental conditions for housing, exhibition, monitoring, nurturing and transportation of objects; the physical treatment of objects for the purpose of stabilizing, conserving and preserving their condition, removal of inauthentic additions or accretions, and compensation for losses; the systematizing of collections and development of effective data retrieval processes; research and training in conservation; and establishment of the facilities to do research in or practice conservation.

"Department" means the United States Department of Health, Education, and Welfare.

"Director" means the Director of the Institute of Museum Services.

"Grantee" means the recipient of a grant under the Act.

"Institute" means the Institute of Museum Services ("IMS") established under section 203 of the Act.

"Museum services" means services provided by a museum including but not limited to preserving and maintaining its collections, exhibiting its collections to the public, and providing educational and other programs to the public through the use of its collections and other resources.

§ 64.5 Eligibility—who may apply.

(a) A museum located in the fifty States of the Union, the Commonwealth of Puerto Rico, the District of Columbia, Guam, American Samoa, the Virgin Islands, the Northern Mariana Islands, or the Trust Territory of the Pacific Islands may apply for a grant under the Act. A public or private nonprofit agency, such as a municipality, college, or university, which is responsible for the operation of a museum may apply on behalf of the museum. A museum operated by a department or agency of the Federal Government may apply only to the extent authorized by general principles of law applicable to the receipt of Federal assistance by these departments or agencies.

§ 64.6 Joint submissions.

Two or more museums may submit a joint application for a grant under the Act.

§ 64.7 General operational support.

In order to maintain, increase or improve museum services, a museum may apply for a grant under the Act to meet its administrative, staff and operating costs.

§ 64.8 Other types of assistance—project support.

(a) In order to increase or improve museum services through projects which are additional to its operating program, a museum may apply for a grant to:

(1) Develop training programs for its staff;

(2) Obtain technical assistance to carry out its functions or provide technical assistance to other museums;

(3) Develop or demonstrate methods of conservation;

(4) Develop and carry out museum programs for specific segments of the public, such as persons in urban neighborhoods, rural areas, Indian reservations, penal and other State institutions, senior citizens, handicapped persons and educationally deprived or economically disadvantaged persons;

(5) Develop and carry out exemplary educational programs;

(6) Cooperate with other museums in developing traveling exhibitions, meeting transportation costs for these exhibitions, and identifying and locating collections available for loan; and

(7) Modernize or preserve its facilities or structures (except in fiscal years 1978 and 1979).

(b) By notice published in the FEDERAL REGISTER and applicable to a particular fiscal year, IMS may limit the types of activities to be funded under this section.

(c) An applicant may apply for one or more types of assistance under § 64.7 and this section.

§ 64.9 Likely size of grants and allocation of funds among activities.

(a) In view of limited funds, it is anticipated that no museum will receive more than $25,000 under the Act for fiscal year 1978 and that most museums which are funded will receive a smaller amount. For future fiscal years, similar limitations may be specified by notice published in the FEDERAL REGISTER.

(b) Not less than 75 percent of the funds available under the Act for grants in a fiscal year will be reserved for grants under § 64.7 (general operational support).

§ 64.10 Allowable costs.

(a) Determinations of costs allowable under a grant are made in accordance with government wide cost principles in appendix C to 45 CFR Part 74 (in the case of applicants which are State or local government agencies), appendix D (in the case of applicants which are institutions of postsecondary education), and appendix F (in the case of applicants which are other nonprofit institutions).

(b) Costs of purchasing objects to be included in the collection of a museum are not allowable (except library, literary or archival material incident to an activity under § 64.7 or § 64.8).

§ 64.11 Basic requirements which a museum must meet to be considered for funding.

(a) *Application.* To apply for a grant, a museum must submit the designated application form containing the information requested in the form. Instructions as to application contents are generally contained in the program announcement published in the FEDERAL REGISTER when applications are invited. (For fiscal year 1978, they are contained in § 64.11 of the proposed regulations. 43 FR 13012).

(b) *IRS letter.* A museum applying as a private, nonprofit institution must supply a letter from the Internal Revenue Service indicating the applicant's eligibility for nonprofit status under section 501(c)(3) of the Internal Revenue Code of 1954.

(c) *Financial statements.* Each applicant museum must supply a financial statement for the museum's most recent completed fiscal year for which information is available (an audited statement is preferred; if the applicant has previously received an IMS Award, the statement must be audited).

(d) *Long range plan.* Each applicant museum must have a long range plan for program and financial development.

(e) *Maintenance of effort.* Each applicant museum must assure that it will maintain its fiscal effort for museum services. An applicant complies with this assurance if its aggregate expenditures for museum services (exclusive of Federal assistance) for the grant period are at least equal to those expenditures for the equivalent preceding period.

§ 64.12 How applications are judged; priorities.

(a) To select grantees and determine the amount of their awards, IMS rates competitive applications under the applicable criteria stated in §§ 64.13 and 64.14. Normally, these applications are first evaluated by readers, panels of experts, or both. Final determinations as to the award of grants are made by the Director after review by the Board.

(b) Priority is given to museums which have been providing museum services for at least 2 years prior to applying to IMS.

(c) In the case of applications for general operational support made after September 30, 1978, priority is given to museums which have exhibition facilities.

(d) To achieve diversity in the distribution of assistance, the Institute considers the location, size, and category of the applicant in addition to the criteria in §§ 64.13 and 64.14.

§ 64.13 Criteria for evaluation of applications for general operational support.

The following criteria apply to the evaluation of all applications for general operational support submitted in fiscal year 1979 and succeeding fiscal years. In applying these criteria, the total operation of the applicant museum is assessed, especially the museum's operation as it would be if the general operational support is granted. This assessment is based primarily on the information supplied in the museum's application. A positive answer to the questions below favors the applicant.

(a) *Museum services.* Are the applicant's museum services of high quality? How will their quality be improved by the general operational support requested?

(b) *Collection and exhibits.* Are the museum's collections and exhibits of high quality and importance? How will the conservation of the collections be enhanced if the general operational support is granted?

(c) *Accessibility.* How accessible to the public are the museum's services, collections, and exhibits? How accessible will they be if the general operational support is granted?

(d) *Population served.* To what extent does the museum serve persons who otherwise have limited access to the type of services which it provides?

(e) *Financial management.* What is the quality of the financial management of the museum?

(f) *Long range plans.* What is the quality of the museum's long range plans for financial and program development?

(g) *Community commitment.* How committed to the museum are its users and supporters? Does the museum have a substantial base of non-Federal support?

(h) *Use of IMS Funds (when applicable).* Has the museum used effectively its IMS funds, if it has received any?

§ 64.14 Criteria for evaluation of applications for project support.

The following criteria apply to the evaluation of all applications for project support submitted in fiscal year 1979 and succeeding fiscal years.

(a) To what extent does the application address a problem which is general to a number of museums but has not been adequately addressed?

(b) To what extent does the project represent a model or exemplary approach to the problem addressed? To what extent may this approach, if successful, be replicated?

(c) What is the quality of the project as measured by:

(1) The qualifications and experience of personnel designated to carry it out;

(2) The appropriateness of size and scope of the project to achieve productive results; and

(3) The reasonableness of estimated cost in relation to anticipated results?

(d) How sound is the project, taking into account:

(1) The extent to which the objectives of the project are sharply defined, clearly stated and capable of being achieved by the proposed procedures; and

(2) The extent to which provision is made for adequate evaluation of the project and for disseminating the results of the project to other interested persons.

(e) Does the applicant lack alternative sources of Federal support for the project?

§ 64.15 Duration of grant.

Grants under the Act normally permit the grantee to use the funds for a period of up to 12 months from the start of the grant period. The grantee may use grant funds during the period specified in the grant document unless the grant is suspended or terminated. If, in the case of a grant under § 64.8, the grantee needs additional time to complete the grant project the grantee may apply for an extension of the grant period without additional funds. The Director may approve this extension at his or her discretion. In exceptional cases, applicants may receive grants for multiyear projects in accordance with applicable procedures of the Department.

§ 64.16 IMS share of the cost of a proposal.

(a) Subject to § 64.9(a) and the applicable requirements in 45 CFR part 74 relating to allowable costs, a museum may receive a grant for up to 50 percent of its proposed operating or activity budget for museum services in the case of a grant under § 64.7, or up to 50 percent of its approved project costs, in the case of a grant under § 64.8. In exceptional cases, when clearly justified under the criteria in § 64.17, a museum may receive a grant for an amount in excess of this 50 percent of limitation. No more than 20 percent of funds appropriated for grants under the Act for a fiscal year may be used by IMS for grants in that fiscal year which exceed the 50 percent limitation.

(b) An applicant requesting general operational support under § 64.7 may submit a total operating budget which shows that the applicant will satisfy the requirements of paragraph (a) (relating to cost sharing) but which need not identify the particular operating costs for which IMS funds will be used. An applicant which receives general operational support on this basis must be prepared to show that its

actual operation generally conformed to the operating proposal on which its application was judged.

(c) Examples include: (1) Museum X has an operating budget of $100,000. After assessing its program; Museum X concludes that adequate performance of museum services, including the exhibition of its collection to the public for an additional day each week, requires an operating budget of $120,000. Museum X applies for $20,000 of general operational support under § 64.7 to partially support this budget. Its total operating budget includes more than $40,000 of costs which are considered allowable under applicable cost principles in 45 CFR part 74. Museum X's application for $20,000 is eligible for consideration.

(2) Museum Y applies for funding a staff member for a conservation laboratory and for costs incidental to developing a new method of paper conservation. The total cost of the project is $25,000. Museum Y applies for $12,500 to cover this cost. It undertakes to furnish the other $12,500 from non-Federal sources. Its application may be considered.

§ 64.17 Criteria for applying exceptions.

In determining whether a proposal which has been selected for an award qualifies for Federal funds in excess of the 50 percent limitation described in § 64.16, the Director applies the following criteria:

(a) The financial condition of the museum to be assisted;

(b) The inability of the museum to obtain other funds due to factors beyond its control;

(c) The quality of the proposal;

(d) The quality of the museum's collection; and

(e) The extent to which the museum serves populations otherwise unserved by museums.

§ 64.18 Applicable grant administration provisions.

(a) The provisions of part 74 of title 45 CFR (45 CFR part 74) and related appendices apply to the award and administration of grants under the Act. Part 74 contains general rules about fiscal and administrative matters pertaining to grants awarded by the Department, including rules about retaining records, accounting for grant-related income, cost sharing (including rules for valuation of in-kind contributions), grantee financial management systems, fiscal and performance reports, grant payment requirements, budget revisions, grant closeout, suspension and termination of a grant, preapplication and application forms, standards for procurement under grants and other pertinent matters.

(b) 45 CFR part 16, relating to a department grant appeals process, applies to the resolution of particular disputes arising under grants awarded under the Act.

§ 64.19 Reports.

In its final report submitted under § 74.82 of title 45, a grantee shall briefly describe how the performance of the grant has satisifed the objectives of the recipient museum as stated in its application and how assistance under the Act has served the purpose of the Act as reflected in the applicable evaluation criteria.

§ 64.20 Applicable civil rights requirements.

Federal financial assistance under the Act is subject to:

(a) Title VI of the Civil Rights Act of 1964 (relating to discrimination on the basis of race) and accompanying regulations (45 CFR part 80);

(b) Title IX of the Education Amendments of 1972 (relating to discrimination on the basis of sex) and accompanying regulations (45 CFR part 86);

(c) Section 504 of the Rehabilitation Act of 1973 (relating to discrimination on the basis of handicap) and accompanying regulations (45 CFR part 84).

(The Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20202, sells copies of the volume of 45 CFR containing these parts and part 74; it is also available in Federal depository libraries.)

§ 64.15 Duration of grant.

Grants under the Act normally permit the grantee to use the funds for a period of up to 12 months from the start of the grant period. The grantee may use grant funds during the period specified in the grant document unless the grant is suspended or terminated. If, in the case of a grant under § 64.8, the grantee needs additional time to complete the grant project the grantee may apply for an extension of the grant period without additional funds. The Director may approve this extension at his or her discretion. In exceptional cases, applicants may receive grants for multi-year projects in accordance with applicable procedures of the Department.

§ 64.16 IMS share of the cost of a proposal.

(a) Subject to § 64.9(a) and the applicable requirements in 45 CFR part 74 relating to allowable costs, a museum may receive a grant for up to 50 percent of its proposed operating or activity budget for museum services in the case of a grant under § 64.7, or up to 50 percent of its approved project costs, in the case of a grant under § 64.8. In exceptional cases, when clearly justified under the criteria in § 64.17, a museum may receive a grant for an amount in excess of this 50 percent limitation. No more than 20 percent of funds appropriated for grants under the Act for a fiscal year may be used by IMS for grants in that fiscal year which exceed the 50 percent limitation.

(b) An applicant requesting general operational support under § 64.7 may submit a total operating budget which shows that the applicant will satisfy the requirements of paragraph (a) (relating to cost sharing) but which need not identify the particular operating costs for which IMS funds will be used. An applicant which receives general operation support on this basis must be prepared to show that its actual operation generally conformed to the operating proposal on which its application was judged.

(c) Examples include: (1) Museum X has an operating budget of $100,000. After assessing its program, Museum X concludes that adequate performance of museum services, including the exhibition of its collection to the public for an additional day each week requires an operating budget of $120,000. Museum X applies for $20,000 of general operational support under $64.7 to partially support this budget. Its total operating budget includes more than $40,000 of costs which are considered allowable under applicable cost principles in 45 CFR part 74. Museum X's application for $20,000 is eligible for consideration.

(2) Museum Y applies for funding a staff member for a conservation laboratory and for costs incidental to developing a new method of paper conservation. The total cost of the project is $25,000. Museum Y applies for $12,500 to cover this cost. It undertakes to furnish the other $12,500 from non-Federal sources. Its application may be considered.

§ 64.17 Criteria for applying exceptions.

In determining whether a proposal which has been selected for an award qualifies for Federal funds in excess of the 50 percent limitation described in § 64.16; the Director applies the following criteria:

(a) The financial condition of the museum to be assisted;

(b) The inability of the museum to obtain other funds due to factors beyond its control;

(c) The quality of the proposal;

(d) The quality of the museum's collection; and

(e) The extent to which the museum serves populations otherwise unserved by museums.

§ 64.18 Applicable grant administration provisions.

(a) The provisions of part 74 of title 45 CFR (45 CFR part 74) and related appendices apply to the award and ad-

ministration of grants under the Act, part 74 contains general rules about fiscal and administrative matters pertaining to grants awarded by the Department, including rules about retaining records, accounting for grant-related income, cost sharing (including rules for valuation of in-kind contributions), grantee financial management systems, fiscal and performance reports, grant payment requirements, budget revisions, grant closeout, suspension and termination of a grant, preapplication and application forms, standards for procurement under grants and other pertinent matters.

(b) 45 CFR part 16, relating to a department grant appeals process, applies to the resolution of particular disputes arising under grants awarded under the Act.

§ 64.19 Reports.

In its final report submitted under § 74.82 of title 45, a grantee shall briefly describe how the performance of the grant has satisfied the objectives of the recipient museum as stated in its application and how assistance under the Act has served the purpose of the Act as reflected in the applicable evaluation criteria.

§ 64.20 Applicable civil rights requirements.

Federal financial assistance under the Act is subject to:

(a) Title VI of the Civil Rights Act of 1964 (relating to discrimination on the basis of race) and accompanying regulations (45 CFR part 80);

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(c) Section 504 of the Rehabilitation Act of 1973 (relating to discrimination on the basis of handicap) and accompanying regulations (45 CFR part 84).

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APPENDIX A—CRITERIA FOR EVALUATION OF APPLICATIONS SUBMITTED IN FISCAL YEAR 1978

PART I. APPLICATIONS FOR GENERAL OPERATIONAL SUPPORT

The following criteria apply to the evaluation of applications for general operational support to determine recipients and amount of awards.

(a) The degree to which the assistance requested will result in more effective performance of museum services;

(b) The quality of the museum's long range plans for program and financial development and the relationship of the proposal to these plans;

(c) The degree to which the assistance will contribute to the museum's financial stability;

(d) The benefit of the proposal to the area or community of which the museum is a part, including the degree to which the museum serves populations otherwise unserved by museums;

(e) The degree to which the need for the requested financial assistance is due to factors such as increased demand for museum services, increased attendance, or other factors beyond the control of the applicant;

(f) The degree to which the applicant lacks alternative Federal sources of support for the proposal;

(g) The degree to which the museum receives financial support from community and other sources;

(h) The existing accessibility of the museum's facilities to the public and the accessibility of the facilities as it would be affected by the proposal;

(i) the quality and importance of the museum's collection, including the extent to which the collection is unique and irreplaceable;

(j) The relationship among size of staff, quality of staff, and museum facilities; and the effect of the proposal on this relationship and on the overall quality of the museum's performance.

PART II. APPLICATIONS FOR PROJECT SUPPORT

The criteria listed in part I of this appendix and the following criteria apply to the evaluation of applications for project support to determine recipients and amounts of awards.

(a) The degree to which the application addresses a problem which is general to a number of museums but has not been adequately addressed;

(b) The degree to which the project represents a model or exemplary approach to a problem and may be replicated;

(c) The quality of the project as measured by the qualifications and experience of personnel designated to carry it out, the sufficiency of size and scope of the project to achieve productive results, and the reasonableness of estimated cost in relation to anticipated results; and

(d) The soundness of the project, including the degree to which the objectives of the project are sharply defined, clearly stated and capable of being achieved by the proposed procedures; and provisions is made for adequate evaluation of the project and for disseminating the results of the project to other interested parties.

APPENDIX B—SUMMARY OF MAJOR COMMENTS FROM THE PUBLIC ON PROPOSED REGULATIONS FOR MUSEUM SERVICES PROGRAM AND RESPONSES

DEFINITION OF "MUSEUM"—SECTION 64.3

1. *Exhibition to the public.* A number of comments generally related to the requirement in the law that a museum must regularly exhibit objects to the public in order to qualify as a museum. One commenter inquired about the eligibility of a university biological collection which is primarily used for research and which is not exhibited to the public. The status of an institution which maintains, and makes available for inspection, probate records, family histories, and genealogical information was the subject of another inquiry. Other questions received by IMS during the course of the comment period related to the nature of the audience served by an institution and the purpose of the collection it maintains. University collections used in particular academic courses or so-called "suitcase" exhibits used by school systems in carrying out their instructional programs were cited.

The Museum Services Act provides that an institution is a museum if, among other things, it "exhibits" objects "to the public on a regular basis." Section 210(4) of the Act. This requirement is basic and is reflected in the regulations for the Museum Services Program. Section 64.3(a)(3). Accordingly, an institution which does not regularly exhibit objects to the public does not qualify as a "museum" for purposes of the Museum Services Act and may not participate in the program of financial assistance under the Act.

As a matter of clarification, the regulations in § 64.3(d) also provide that "an institution does not exhibit objects to the public for the purposes of this section (§ 64.3 relating to the definition of museum) if the display or use of the objects is incidental to an overall purpose of the institution which is other than their exhibition to the public." [1] This provision is designed to clarify the status, under the Act, of institutions which are organized for educational or esthetic purposes and may, in a literal sense, display objects in the course of their overall activities but which are not really museums and were never intended to be covered under the Act, as IMS understands it. For example, ordinarily a public library displays objects it owns to the public but that activity does not render the library a museum under the Act. Similarly, such display or exhibition of objects as may be incidental to theatrical, musical, or television productions or to the maintenance and operation of public parks and playgrounds, must normally be considered outside the ambit of the Act.

Turning to other examples raised in comments or inquiries, a university which maintains, for research purposes, a collection which is not exhibited to the public does not satisfy the statutory definition of a museum. It is recognized that maintenance of these collections constitutes a great contribution to the museum profession. However, in view of the limited funds available for grants under the Act, the Institute believes that the limitation in the Act to institutions which exhibit to the public is appropriate.

Similarly, a university or school system may maintain a collection primarily used for instructional purposes or as a resource in carrying out an academic program. For example, a collection of objects maintained by the university's anthropology department may be displayed to the students in that department as they walk in and out of class or may be used in classroom work. A school or school system may exhibit objects to its students through so-called suitcase exhibits.

In the view of the Institute, these activities do not constitute exhibition to the public within the meaning of the Act. Exhibition to a restricted category of persons (the students in the anthropology class) under circumstances in which the general public has limited or occasional access is not exhibition to the public as IMS understands it. At a minimum, exhibition to the public involves general accessibility to the public at large and public notice of that accessibility, elements lacking in the examples stated.

[1] The final version of this paragraph (§ 64.3(d)) reflects editorial changes.

The maintenance of probate or genealogical records by a public institution such as a court would also be outside the ambit of the Act. Even if such an institution can be regarded as organized for educational or esthetic purposes, which is questionable, the exhibition would seem to be incidental to purposes other than exhibition to the public.

Because the funds available under the Act are limited, the program must be focused on those institutions which exist primarily to provide museum services to the public. For all these reasons, the Institute does not regard institutions such as public libraries and archives normally as qualifying as museums.

2. *Mentioning specific types of museums.* Many commenters requested the mention of specific types of museums, including natural and physical science centers, environmental education and/or nature centers, historic building museums, historical museums, health and medical museums and the like.

The regulations already contain a list of the common categories of museums in § 64.3(b). The Institute believes it would be unwise to mention every type of museum. The Institute wishes to avoid the implication that a type of institution which properly falls within the ambit of the Act is excluded because it is not mentioned. However, the Institute regards this reponse as an opportunity to indicate that the types of institutions commenters mentioned (as described above) are generally understood to fall within the definition. Because of considerable confusion surrounding the status of historic building museums, these institutions are mentioned in the final regulations. (See § 64.3(b)(3).)

3. *Professional staff.* A county historical commission which displays objects in a county courthouse felt that maintaining a full-time staff person even on a voluntary basis as provided by § 64.3(c) was beyond its capacity and that this requirement would exclude small institutions from participation in the program under the Museum Services Act. The commenter urged recognition of use of part-time staff.

On the other hand, another commenter questioned the use of volunteers to qualify a museum for a grant, noting that, although volunteers make significant contributions to a museum, Federal support of an institution solely operated by volunteers is questionable. This commenter viewed at least one full-time paid professional as representing a minimum commitment to a professional operation in the public trust. The commenter pointed out that the American Association of Museums, through its accreditation procedure, requires that a museum have at least one full-time paid staff member.

The requirement that an institution "use" a professional staff is in the statute and cannot be waived. (Museum Services Act, section 210(4).) The regulations give the broadest possible interpretation to this requirement to avoid excluding institutions which cannot afford a full-time paid professional. (§ 64.3(c)) The exclusion of such museums, it is believed, would bar from participation in the program a vital segment of the spectrum of institutions which serve the museum public, particularly historic houses. Comments were received by the Institute which stressed that historic building museums are frequently operated by volunteers and are without paid professional staff. No change is made in the definition in this respect.

The Institute also declines to impose any further requirements on recipients to obtain a paid professional staff. However, the Institute considers it desirable that an institution which becomes a participant in the Museum Services Program move in the direction of supplying the "minumum commitment" cited by the commenter. Language has been added to § 64.3(c) to reflect this policy.

4. *Joint applications by museums.* Several commenters asked that the regulations provide for the eligibility of consortiums, museum associations, collaboratives and other nonprofit agencies and organizations which provide support or services to museums.

While both the Act and the regulations speak of "museum" in the singular, nothing in the Act or in the proposed regulations prevents a group of museums from applying for assistance under the program. On the contrary, such a group of museums would be eligible.

In the case of such an application, applicants may have separate budgets corresponding to the programs, services or activities performed by each of the applicants or may have a combined budget.

Clarifying language is added to the final regulation to make clear that joint applications from museums are accepted.

While a group of museums may apply for assistance under the Act, an application from an institution which is not itself a museum may not be considered since the Act authorizes grants only to museums. Thus, a nonprofit agency which provides support for, or assistance to, museums but which is not itself a museum (as defined in § 64.3) is not eligible for a direct grant. However, a museum which receives a grant is authorized to contract for services with other agencies including nonprofit "support" agencies. Grantees may use such agencies to supply services under the grant, consistent with the general requirement that the grantee remain responsible for grant performance.

The Institute will explore the possibility of proposing a legislative amendment to the Act to authorize assistance for nonprofit "support" agencies which are not museums.

ELIGIBILITY—SECTION 64.5

5. *Municipal and university applicants.* Some commenters expressed concern that the regulations in defining "museum" may prevent the participation of public agencies such as city or county governments which operate museums or colleges and universities with museums which are not separately organized and do not have separate budgets. However, § 64.5 is intended to address this problem by providing: "A public or private nonprofit agency, such as a municipality, college, or university, which is responsible for the operation of a museum may apply on behalf of the museum."

The Institute believes that this language addresses the problem of the commenter. To qualify, a museum need not have had a separate budget but must be prepared to make the budget related showings required by the application and by any post-award review.

6. *Museums abroad.* Another commenter proposed that the regulations provide for the eligibility of museums located outside the United States. In the example mentioned by the commenter, the museum located abroad is situated on property owned by the United States Department of State and leased to a nonprofit corporation which operates the museum. The proposed regulations confined eligibility to institutions located in the United States. The Institute believes that Congress intended to focus assistance on those institutions which primarily serve the U.S. public, particularly in view of the limited funds available for the purpose of the program at this stage. No change is made in the regulations.

OTHER TYPES OF ASSISTANCE—PROJECT SUPPORT—SECTION 64.8

7. *Preservation of historic sites.* Several commenters suggested that the reference to conservation projects in § 64.8(a)(3) be expanded to include conservation or preservation of historic structures as well as conservation or preservation of objects. The commenters supported the proposed regulation in its effort to encourage conservation projects (through the language of § 64.8(a)(3)) but felt that the proposed regulation did not go far enough in reflecting the special needs of museums which are or maintain and exhibit historic structures.

Another commenter said that § 64.8(a)(7) (relating to modernization of facilities) should include reference to restoration or preservation of museum facilities when the facilities are of historical or cultural significance. The commenter felt that such participation by the IMS would not duplicate Federal historic preservation programs.

The Museum Services Act lists conservation as one of the activities for which grant funds may be used. (Section 206(a)(5) (conservation of artifacts and art objects).)

The regulations in § 64.8(a)(3) reflect this authority by providing that a museum may apply for project support to "develop or demonstrate methods of conservation."

Section 64.8(a)(7) of the proposed regulations provided for project support to help a museum "modernize its facilities (except in fiscal year 1978)." While the emphasis of the Act is on conservation of objects, nothing in the statute precludes the Institute from extending the concept of "conservation" to preservation of historic building museums. The Institute believes that the regulations should provide for the possible support of this activity.

However, in view of the high cost of construction, as well as limited funds expected to be available to the program for fiscal year 1979 and the current fiscal year, the final regulations exclude this type of activity for fiscal years 1978 and 1979. For fiscal years after fiscal year 1979 preservation and modernization of structures may be included unless excluded by a general notice published in the FEDERAL REGISTER for that year.

8. *Training Programs.* Another commenter suggested that training programs under § 64.8 be focused on upgrading existing staff in the field through inservice training.

Section 64.8(a)(1) authorizes project support for grants to a museum to "develop training programs for its staff." Thus, a museum may apply for grant funds to support inservice training of existing staff. However, the Institute believes that to confine training activities only to inservice training would restrict program flexibility. Accordingly, no change is made in the regulation.

9. *Conservation.* One commenter objected to the provision for funding new special conservation projects. The commenter thought that the emphasis should be on maintenance of a museum's conservation laboratory and staff.

The development or demonstration of methods of conservation mentioned in § 64.8(a)(3) does not exclude other types of conservation support. Operational support grants (§ 64.7) are available for the activities mentioned by the commenter.

BASIC REQUIREMENTS—SECTION 64.11

10. *Long-range plans.* A commenter supported the provision in the proposed regulations requiring a museum applicant to submit a long-range plan as part of its grant application. The commenter observed that the Institute should encourage museums to adopt a standard financial report format as well as a standard long-range plan format.

Section 64.11(d) of the proposed regulations requires an applicant museum to submit a copy or brief description of the museum's long-range plans for program and financial development. In line with the commenter's thinking, the final regulations require the applicant to have a long-range plan. The Institute agrees with the commenter that this requirement will have a constructive influence on the quality of museum services carried out under the program.

To some extent financial and other report forms under the program are standardized under applicable requirements in part 74 of Title 45 CFR. (See § 64.18) The Institute will also attempt to establish uniform standards for required financial and other reporting by museums since it believes the commenter's suggestion to be well taken. The Institute will continue to review the possibility of providing further guidance regarding a uniform format for the long-range plan description called for in § 64.11(d).

CRITERIA—SECTIONS 64.13 AND 64.14

11. One commenter observed that the criteria were too vague, particularly in terms of describing financial need, and urged that the final regulations require that applications indicate a need for funds for a particular purpose or purposes. Specific suggestions about individual criteria were furnished by a number of commenters.

The criteria are necessarily broad and general in order to accommodate the Institute's need to review applications from a wide variety of institutions and a concern that criteria which are too focused may tend to "over direct" the program.

On the other hand, individual comments from public commenters and experience with the initial year of reviewing applications have convinced the Institute that changes in the criteria applicable to fiscal year 1979 and future fiscal years are warranted. Accordingly, a new set of criteria for both general operational and project support is established for those years. Comments from the public objected to the use of criteria measuring the relative lack of access to Federal support and sought clarification of criteria relating to the applicant's need, the extent of local financial support, and the nature of unserved or underserved populations. Subject to reconsideration in the light of further public comment, the criteria set forth in § 64.13 of the regulations take into account these objections.

For fiscal year 1979 and future fiscal years, separate sets of criteria are set forth for general operational support and for project support. In the general operational support category, the emphasis is on assessing the overall situation of the applicant museum. Lack of access to other Federal assistance is no longer a criterion for judging operational support grants since, aside from IMS, there are no other Federal programs which provide operational assistance. In response to comments, the criterion relating to unserved populations is broadened.

OTHER COMMENTS

12. One commenter observed that while the regulations appeared to be clear and concise, attention should be paid to providing information to readers as to how to obtain copies of other regulations which are cross-referenced by the new part 64. The commenter's point is well taken and the Institute is taking steps to be certain that each grantee receives a package containing copies of all applicable regulations.

[FR Doc. 78-27284 Filed 9-28-78; 8:45 am]

federal register

FRIDAY, SEPTEMBER 29, 1978
PART V

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Health Care Financing Administration

■

MEDICAID REGULATIONS

Reorganization and Rewriting

[4110-35]

Title 42—Public Health

CHAPTER IV—HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER C—MEDICAL ASSISTANCE PROGRAM

MEDICAID REGULATIONS

Reorganization and Rewriting

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

ACTION: Final rule.

SUMMARY: These regulations reorganize and redesignate, with clarifying editorial changes, the current regulations for the medicaid program (title XIX of the Social Security Act). No policy changes have been made in the existing regulations. Those regulations will now be systematically and intensively reviewed for possible revisions during the second phase of HCFA's medicaid recodification project.

DATE: Effective October 1, 1978. Although this rule is final, comments may be submitted as described in the supplementary information below.

ADDRESSES: Send comments to: Acting Director, Policy Coordination Staff, Medicaid Bureau, Health Care Financing Administration, Department of Health, Education, and Welfare, Room 2618, Switzer Building, 330 C Street SW., Washington, D.C. 20201. In commenting, please refer to MMB-240. Comments will be available for public inspection, beginning approximately 2 weeks after publication, at the above address from Monday through Friday of each week from 8:30 a.m. to 5 p.m., telephone 202-245-0722.

FOR FURTHER INFORMATION CONTACT:

Margaret O. Schnoor, 202-245-0722.

SUPPLEMENTARY INFORMATION: As indicated in a recodification proposal published January 17, 1978 (43 FR 2413), HCFA is rewriting all existing medicaid regulations in clearer, simpler language. Our purpose is to make the regulations more understandable by all those affected (including State agencies, applicants and recipients, and providers of services), and more useful for program administrators. No substantive changes have been made in this first phase of a medicaid recodification project under the Department's operation common sense initiative. In the second phase, we plan to develop policy changes based on our analysis of the current rules in preparing this document, letters responding to operation common sense, and problems found during ongoing program operation. Those changes will be published as proposed rule making for public comment over the next two years, and will represent for medicaid the substantive recodification to which HEW is committed for all programs.

CONTENT

This document contains all medicaid regulations currently in 42 CFR chapter IV, subchapter C, except for the utilization control penalty provisions in § 450.20(b). Passage of the medicare-medicaid anti-fraud and abuse amendments, Pub. L. 95-142, October 25, 1977, made the penalty provisions in § 450.20(b) obsolete. A notice of proposed rulemaking implementing the changes made by Pub. L. 95-142 is being published. Until the new penalty regulation becomes final, the statutory requirements of sec. 1903(g) of the Social Security Act will be used as the basis for imposing penalties. The document includes all new medicaid regulations and revision published as final rules during the last few months. It does not include regulations recently published as proposed rules but not yet published in final.

In a separate project, the "joint" rules in title 45 of the Code of Federal Regulations (parts 201, 204, 205, 206 and 208) that currently apply to other State plan programs of financial assistance and services, as well as to medicaid, will also be rewritten as they pertain to medicaid and transferred to title 42.

For the convenience of readers, redesignation tables at the end of this preamble indicate the relationship between the old and the new sections. The first set of tables is arranged in order of the previous section numbers and the second set is arranged by the new numbers.

EFFECTIVE DATE

The rewritten regulations are being made effective October 1, 1978, to coincide with the deadline date for publishing material to be included in the annual revision. This will provide readers with a complete set of the revised regulations in that publication.

WAIVER OF PROPOSED RULEMAKING

As explained above, the purpose of this publication is to simplify and clarify the existing regulations without making any substantive change. We have carefully reviewed the revised language in order to satisfy ourselves that we have not modified existing policy unintentionally. Moreover, as also discussed above, we believe it highly desirable to include the entire set of regulations in the October 1 edition of title 42. Time and staff constraints have not permitted us to go through proposed rulemaking and still complete the task by that date.

For those reasons, we have concluded that it is both unnecessary and impractical to publish this document as notice of proposed rulemaking. We are therefore waiving rulemaking procedures in accordance with section 4(a) of the Administrative Procedure Act (5 U.S.C. 553(b)).

We will, however, consider comments or objections from anyone who believes that this rewriting changes current policy. Suggestions for additional improvements in style, terminology, and general format are also welcome. After 3 months, we will review comments and publish the necessary changes or a notice that no changes are required.

REDESIGNATION AND DERIVATION TABLES

PART 446

Old section	New section
446.10	431.12
446.151	432.2
446.160	432.10
446.165	432.31
446.166	432.32
446.170	432.30
446.175	432.50
446.180	432.55
446.185	432.60

PART 448

Old section	New section
Beginning note	435.2.
448.1(a)(1)(i)	435.4.
448.1(a)(1)(ii)	435.732.
448.1(a)(1)(ii)(A)	435.321.
448.1(a)(1)(ii)(B)	435.Unnecessary.
448.1(a)(2)(i)	435.4.
448.1(a)(2)(ii)	435.831.
448.1(a)(3)	435.740.
448.1(b) first sentence	435.10.
448.1(b)(1)(i)	435.110.
448.1(b)(1)(ii)	435.111.
448.1(b)(1)(iii)	435.112.
448.1(b)(2)	Unnecessary.
448.1(b)(2)(i)	435.120.
448.1(b)(2)(ii)	435.230.
448.1(b)(2)(iii)	435.121.
448.1(b)(2)(iv)	435.130.
448.1(b)(2)(v)	435.131.
448.1(b)(2)(vi) except (B)	435.132.
448.1(b)(2)(vi)(B)	Redundant with 435.132 first sentence.
448.1(b)(2)(vii)	435.133.
448.1(b)(2)(viii) words before "In States".	Unnecessary.
448.1(b)(2)(viii)	435.135.
448.1(b)(3) introductory sentence.	Unnecessary.
448.1(b)(3)(i)	435.113, 435.122.
448.1(b)(3)(ii)	435.114, 435.134.
448.1(c) first sentence	435.10, 435.200.
448.1(c)(1)	435.210.
448.1(c)(2) except second sentence.	435.211.
448.1(c)(2) second sentence.	Unnecessary.
448.1(c)(3)	435.223.
448.1(c)(4)	435.222.
448.1(c)(5)	435.221.
448.1(c)(6)	435.220.
448.1(d)(1).	435.301.
448.1(d)(2)	435.325.

PART 448—Continued

Old section	New section
448.1(e)	435.10.
448.2(a)	435.401.
448.2(b)(1)	435.501.
448.2(b)(2)	Unnecessary.
448.2(c)	435.401.
448.2(d)	435.230.
448.2(e) words before ". . . if a State plan.	Unnecessary.
448.2(e) words after "Notwithstanding the provisions specified in paragraph (d) of the section . . .".	435.231, 435.722.
448.3(a)(1)	435.10.
448.3(a)(1)(i)	435.711.
448.3(a)(1)(ii)(A)	435.721(a).
448.3(a)(1)(ii)(B)(*1*)	435.721(a).
448.3(a)(1)(ii)(B)(*2*), words before "provided that".	435.721(b).
448.3(a)(1)(ii)(B)(*2*), words beginning "provided that".	435.1006.
448.3(a)(1)(ii)(C), first sentence.	435.10.
448.3(a)(1)(ii)(C), second sentence.	435.121(b).
448.3(a)(2)	Unnecessary.
448.3(b)(1)	Unnecessary.
448.3(b)(1)(i) first sentence.	Unnecessary.
448.3(b)(1)(i) second sentence.	435.723(b).
448.3(b)(1)(i) third sentence.	435.712(a), 435.724(b).
448.3(b)(1)(i) fourth sentence.	435.724(b).
448.3(b)(1)(ii)	435.603.
448.3(b)(1)(iii)	435.602.
448.3(b)(2)(i)	435.723(c).
448.3(b)(2)(ii)	435.723(d).
448.3(b)(2)(iii)	435.721(c).
448.3(b)(2)(iv) first sentence.	435.831(a)(2).
448.3(b)(2)(iv) second sentence.	Unnecessary.
448.3(b)(2)(iv) third sentence words before ". . . after deducting all . . .".	435.811.
448.3(b)(2)(iv) third sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(3)(i)	435.724(b).
448.3(b)(3)(ii)	435.724(c).
448.3(b)(3)(iii)	435.724(c).
448.3(b)(3)(iv)	435.721(c).
448.3(b)(3)(v) first sentence words before ". . . except that the income . . .".	435.721(c).
448.3(b)(3)(v) first sentence words after ". . . medically needy determinations . . .".	Unnecessary.
448.3(b)(3)(v) second sentence words before ". . . after deducting all . . .".	435.811.
448.3(b)(3)(v) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(4) first paragraph.	435.734.
448.3(b)(4) second paragraph.	Unnecessary.
448.3(b)(5)(i)	435.712(a).
448.3(b)(5)(ii)	435.712(c).
448.3(b)(5)(iii)	435.712(b).
448.3(b)(5)(iv) first sentence.	Unnecessary.
448.3(b)(5)(iv) second sentence words before ". . . to the assistance unit . . .".	435.811.

PART 448—Continued

Old section	New section
448.3(b)(5)(iv) second sentence words after ". . . to the assistance unit . . .".	435.831(c).
448.3(b)(6)	435.404.
448.3(b)(7)	435.725, 435.731, 435.733, 435.813, 435.815, 435.832.
448.3(b)(8)	435.725, 435.732, 435.733, 435.832.
448.3(b)(9)	435.732.
448.3(c)(1)	Unnecessary.
448.3(c)(1)(i)	435.811.
448.3(c)(1)(ii)	435.812(a), 435.814(a), 435.816(a).
448.3(c)(1)(ii)(A)	435.816.
448.3(c)(1)(ii)(B) words before "except that".	435.812, 435.814.
448.3(c)(1)(ii)(B) words beginning "except that".	Unnecessary.
448.3(c)(1)(iii)	435.812(b), 435.814(b).
448.3(c)(1)(iv) words before "and the amount of liquid . . .".	435.834, 435.835.
448.3(c)(1)(iv) words after ". . . of the Social Security Act . . ." and before ". . . except that . . .".	435.834(c), 435.835(c).
448.3(c)(1)(iv) words after ". . . in a family . . ." to end of sentence.	435.834(b).
448.3(c)(1)(iv) last sentence.	Unnecessary.
448.3(c)(2)	435.831.
448.3(c)(3) first sentence.	Redundant.
448.3(c)(3)(i)	435.831(a)(1), 435.841(c).
448.3(c)(3)(ii)	435.831(a)(2),(3), 435.841(d),(e).
448.3(c)(4)	435.831(a), 435.841(b).
448.4(a)	435.1001.
448.4(b)(1)	435.1002.
448.4(b)(1)(i)	Unnecessary.
448.4(b)(1)(ii)	Unnecessary.
448.4(b)(1)(iii)	Unnecessary.
448.4(b)(2)	435.1008.
448.4(b)(3) first sentence.	435.1005 and 435.1006.
448.4(b)(3) second sentence.	Unnecessary.
448.4(b)(4)	435.1007.
448.4(b)(5)	435.1002(b).
448.4(b)(6)	435.1004.
448.4(b)(7) except last sentence.	435.1003.
448.4(b)(7) last sentence	Unnecessary.
448.4(b)(8)	Unnecessary.
448.4(c)	Unnecessary.
448.4(d)	435.1010.
448.4(e)	435.1011.
448.10(a)	Unnecessary.
448.10(b)(1)(i)	436.110.
448.10(b)(1)(ii)	436.115.
448.10(b)(1)(iii)	436.111.
448.10(b)(2)(i)	436.210.
448.10(b)(2)(ii)	436.211.
448.10(b)(2)(iii)	436.212.
448.10(b)(2)(iv)	436.222.
448.10(b)(2)(v)	436.221.
448.10(b)(2)(vi)	436.220.
448.10(b)(3)	436.112.
448.10(b)(4)	436.116.
448.10(b)(5) 1st sentence.	436.301, 436.310, 436.320, 436.330.
448.10(b)(5) 2d sentence	Unnecessary.
448.10(b)(6)	436.10.
448.10(b)(7)	Obsolete.
448.10(c)(1)	436.401(b).
448.10(c)(2)	Obsolete.
448.10(c)(3)	436.401(c).
448.10(c)(4)	436.401(a).
448.10(c)(5)	436.602.
448.10(d)(1)	436.1001(a), 436.1002(a)
448.10(d)(2) except undesignated paragraph after.	Unnecessary.
448.10(d)(2) undesignated paragraph after (vi).	436.1004(a).

PART 448—Continued

Old section	New section
448.10(d)(3)	436.1002(b).
448.10(d)(4)	436.1003.
448.11	436.230.
448.21(a)(1)(i)	436.711.
448.21(a)(1)(ii)	Redundant.
448.21(a)(2)(i) (A)–(C) 1st sentence except words before "and amounts received".	Redundant.
448.21(a)(2)(i) (C) 1st sentence, words after "applicant or recipient", and 2d sentence.	436.603.
448.21(a)(2)(ii)	436.602.
448.21(a)(2)(iii)	Redundant.
448.21(a)(2)(iv)	436.711.
448.21(a)(2)(v)	436.711.
448.21(a)(2)(vi)	436.404.
448.21(a)(3)(i) introductory paragraph.	Unnecessary.
448.21(a)(3)(i)(A)	436.811.
448.21(a)(3)(i)(B)	436.812.
448.21(a)(3)(i)(C) 1st and 2d sentences.	436.813.
448.21(a)(3)(i)(C) 3d–4th sentences.	436.832.
448.21(a)(3)(i)(D) 1st sentence.	436.840.
448.21(a)(3)(i)(D) last sentence.	Unnecessary.
448.21(a)(1) (ii)–(iv)	436.831.
448.21(b)	Redundant.
448.21(c)	436.1002.
448.30 (a), (b) (2) and (3).	435.520, 436.520.
448.30(b)(1) 1st sentence.	Redundant with 435.1002.
448.30(b)(1) 2d sentence	Unnecessary.
448.40(a)(1) words before "but are absent", and (b) (1) and (2).	435.403, 436.403.
448.40(a) words after "residents of the State".	431.52.
448.40(b) introductory paragraph.	Redundant with 435.403(a).
448.50	435.402, 436.402.
448.60(a) (1)–(3) (i) and (iv).	435.1008, 436.1004.
448.60(a)(3)(ii) except "or mental diseases".	435.1009 "institution for tuberculosis".
448.60(a)(3)(ii) except "tuberculosis or".	435.1009 "institution for mental diseases".
448.60(a)(3)(iii)	435.1009 "institution for mental diseases".
448.60(b) (1)–(11)	435.1009, 436.1005.
448.70(a)(1) words before "and in Guam".	435.530.
448.70(a)(1) words after parenthetical note.	436.530.
448.70(a)(2) (i) and (ii) 1st sentence.	435.531(a) (1) and (2), 436.531 (a) and (b).
448.70(a)(2)(ii) 2d sentence.	435.531(a)(3), 436.531(c).
448.70(a)(3)	435.531(a)(3), 436.531(c).
448.70(b)	435.531(b).
448.70(c)(1) 1st sentence	Redundant with 435.1002.
448.70(c)(1) 2d sentence	435.531(a)(3)(ii).
448.70(c)(1) parenthetical note.	435.1003.
448.70(c)(2)	435.1001(b), 436.1001 (b).
448.80(a)(1) words before "and in Guam".	435.540.
448.80(a)(1) words after parenthetical note.	436.540.
448.80(a)(2) and (b)	435.541, 436.541.
448.80(c)(1) 1st sentence	Redundant with 435.1002.
448.80(c)(1) 2nd sentence	435.541(c).
448.80(c)(2)	435.1001(b), 436.1001(b).

PART 449

Old section	New section
449.10(a)(1)	440.210.
449.10(a)(2)	440.220.
449.10(a)(3) introductory paragraph.	441.51.
449.10(a)(3)(i)	441.54.
449.10(a)(3)(ii)	441.55.
449.10(a)(3)(iii)	441.56.
449.10(a)(3)(iv)	441.53.
449.10(a)(4)	441.15.
449.10(a)(5)(i)	440.230.
449.10(a)(5)(ii)	431.53.
449.10(a)(6) introductory paragraph.	440.240.
449.10(a)(6) (i)–(vii)	440.250.
449.10(a)(7)	440.240.
449.10(a)(8)	440.260.
449.10(a)(9)	441.20.
449.10(a)(10)	441.30.
449.10(a)(11)	431.110, 442.201(c), 442.251(d).
449.10(b) introductory paragraph.	440.2.
449.10(b)(1)	440.10.
449.10(b)(2)	440.20.
449.10(b)(3)	440.30.
449.10(b)(4)(i)(A)	440.40.
449.10(b)(4)(i)(B)	442.201 (a), (b).
449.10(b)(4)(i)(C) 1st sentence, words before "except that with".	440.40.
449.10(b)(4)(i)(C) 1st sentence, words after "payments under the plan".	441.11.
449.10(b)(4)(i)(C) 2d and 3d sentences.	442.30.
449.10(b)(4)(ii) 1st sentence.	440.40.
449.10(b)(4)(ii) 2d and 3d sentences.	441.52.
449.10(b)(5)	440.50.
449.10(b)(6)	440.60.
449.10(b)(7) except (i) introductory paragraph, last sentence.	440.70.
449.10(b)(7)(i) introductory paragraph, last sentence.	Redundant.
449.10(b)(8)	440.80.
449.10(b)(9)	440.90.
449.10(b)(10)	440.100.
449.10(b)(11)	440.110.
449.10(b)(12)	440.120.
449.10(b)(13)	440.130.
449.10(b)(14)	440.140.
449.10(b)(15)(i)(A) 1st sentence.	440.150.
449.10(b)(15)(i)(A) last sentence.	442.251 (a), (c), 442.252.
449.10(b)(15)(i)(B)	440.150.
449.10(b)(15)(i)(C)	442.252.
449.10(b)(15)(i)(D)	Redundant.
449.10(b)(15)(i)(E)	440.150.
449.10(b)(15)(ii)	442.254.
449.10(b)(15)(iii)	440.150.
449.10(b)(15)(iv)	440.150.
449.10(b)(15)(v)	Redundant.
449.10(b)(15) undesignated paragraph after (v).	441.11.
449.10(b)(15)(vi)	442.30.
449.10(b)(16) introductory paragraph.	440.160.
449.10(b)(16) (i), (ii)	441.151.
449.10(b)(16)(iii) introductory paragraph.	441.152.
449.10(b)(16)(iii)(A) words before "and for whom".	Obsolete.
449.10(b)(16)(iii)(A) words after "of these regulations".	441.153.
449.10(b)(16)(iii)(B)	Obsolete.
449.10(b)(16)(iii) (C)–(E)	441.153.

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Old section	New section
449.10(b)(16)(iv)(A), except 2d sentence.	441.154.
449.10(b)(16)(iv)(A) 2d sentence.	Redundant.
449.10(b)(16)(iv)(B)	441.155.
449.10(b)(16)(iv)(C)	441.156.
449.10(b)(17)	440.170.
449.10(c) (1) and (2)	441.13.
449.10(c)(3)	Surplusage.
449.10(c)(4)	441.40.
449.10(c)(5) except (ii) (A)–(G).	441.182.
449.10(c)(5)(ii) (A)–(G)	441.181.
449.10(d)(1)(i)	435.1009, 440.2.
449.10(d)(1) (ii), (iv)–(vi)	435.1009.
449.10(d)(1)(iii)	440.2.
449.10(d)(2)	440.270.
449.10(d)(3)	441.11.
449.12(a) introductory paragraph.	442.300.
449.12(a)(1)	442.301.
449.12(a)(1)(i) 1st sentence.	442.302.
449.12(a)(1)(i) 2d sentence.	Unnecessary.
449.12(a)(1)(ii)(A)	442.305.
449.12(a)(1)(ii)(A)(*1*)(i)	442.306.
449.12(a)(1)(ii)(A)(*1*) (ii), (iii).	442.307.
449.12(a)(1)(ii)(A)(*2*)	442.308.
449.12(a)(1)(ii)(A)(*3*)	442.309.
449.12(a)(1)(ii)(A)(*4*)	442.310.
449.12(a)(1)(ii)(B)	442.311, 442.404.
449.12(a)(1)(ii)(C)	442.312, 442.405.
449.12(a)(1)(iii)	442.320, 442.406 (d), (e).
449.12(a)(1) (iv), (v)	442.313.
449.12(a)(1)(vi)	442.314.
449.12(a)(1)(vii)	442.315, 442.415.
449.12(a)(2)	442.316, 442.425 (a), (b).
449.12(a)(3)	442.317, 442.417, 442.476(c).
449.12(a)(4)(i) (A)–(E)	442.318 (a)–(c), 442.319.
449.12(a)(4)(i)(F)	Obsolete.
449.12(a)(4) (ii), (iii)	442.318 (d), (e).
449.12(a)(5) introductory paragraph.	442.321(a), 442.507(a).
449.12(a)(5)(i)	442.322, 442.508.
449.12(a)(5)(ii)	442.323(a), 442.509(a).
449.12(a)(5)(iii)	442.321(b), 442.507(b).
449.12(a)(5) undesignated paragraph following paragraph (iii).	442.323(b), 442.509(b).
449.12(a)(6)(i)	442.324(a), 442.325, 442.326(a), 442.446, 442.447(a) (1), (3), 442.448 (a), (d).
449.12(a)(6)(ii)	442.327.
449.12(a)(6)(iii)	442.326 (b), (c).
449.12(a)(6)(iv)	442.324(b).
449.12(a)(6) (v), (vi)	442.328.
449.12(a)(6) (vii), (viii)	442.329.
449.12(a)(6)(ix)	442.330, 442.511.
449.12(a)(7)(i)	442.331(a).
449.12(a)(7) (ii)–(iv)	442.332.
449.12(a)(7)(vi), (vii)	442.331(b).
449.12(a)(8)(i)	442.333.
449.12(a)(8)(ii)	442.334.
449.12(a)(8)(iii)	442.335.
449.12(a)(8)(iv)	442.337(b).
449.12(a)(8)(v)	442.336.
449.12(a)(8)(vi)	442.337(a).
449.12(a)(9) introductory paragraph.	442.338, 442.474(b).
449.12(a)(9)(i) and (A)–(C).	442.339, 442.481 (a)–(e).
449.12(a)(9)(ii)	442.340, 442.481(f).
449.12(a)(9)(iii)	442.481(g).
449.12(a)(9)(iv)	442.341, 442.481(h).
449.12(a)(9)(v)	442.342, 442.478(a).
449.12(b) introductory paragraph.	Unnecessary.
449.12(b)(1)	442.303.
449.12(b)(2)	442.304.
449.12(b)(3)	442.343.
449.12(b)(4)	442.344.
449.12(b)(5)	442.345.
449.12(b)(6)	442.346.

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Old section	New section
449.12(c) introductory paragraph.	442.400.
449.12(c)(1)	442.418 (a), (b).
449.12(c)(2)	442.410 (a), (b).
449.12(c)(3) introductory paragraph, 1st sentence.	442.411.
449.12(c)(3) introductory paragraph, 2d sentence, and (i)–(ix).	442.401.
449.12(c)(4)–(6)	Obsolete.
449.13 introductory paragraph, 1st sentence, words before "the standards for".	Obsolete.
449.13 introductory paragraph, 1st sentence, words after "July 18, 1977".	442.400.
449.13 introductory paragraph 2d sentence.	Obsolete.
449.13(a)(1)(i)	442.402.
449.13(a)(1)(ii)	442.403.
449.13(a)(1)(iii)	442.406 (a)–(c).
449.13(a)(1)(iv)	442.407.
449.13(a)(1)(v)	442.408.
449.13(a)(1)(vi)	442.409(a) (1), (2).
449.13(a)(1)(vii)	442.409(a)(3).
449.13(a)(1)(viii)	442.410(a)(2).
449.13(a)(1)(ix)	442.412.
449.13(a)(1)(x)	442.413.
449.13(a)(1)(xi)	442.414.
449.13(a)(2)(i) introductory paragraph, 1st sentence.	442.418(a).
449.13(a)(2)(i) introductory paragraph, 2d sentence, and (A) and (B).	442.420.
449.13(a)(2)(ii)	442.419.
449.13(a)(2)(iii)	442.418 (a), (b)(1).
449.13(a)(2)(iv)	442.418 (b)(2), (c).
449.13(a)(2)(v)	442.421.
449.13(a)(2)(vi)	442.422.
449.13(a)(2)(vii)	442.423.
449.13(a)(2)(viii)	442.424(c), 442.425(c).
449.13(a)(2)(ix)	442.424 (a), (b).
449.13(a)(2)(x)	442.425(c).
449.13(a)(2) (xi), (xii)	442.426.
449.13(a)(3)(i)	Unnecessary.
449.13(a)(3)(ii)	442.427(b).
449.13(a)(3) (iii), (iv)	442.428.
449.13(a)(3)(v)	442.429.
449.13(a)(3)(vi)	442.427(a).
449.13(a)(3)(vii)	442.430.
449.13(a)(3)(viii)	442.431.
449.13(a)(3) (ix), (x)	442.432.
449.13(a)(3)(xi)	442.427(c).
449.13(b)(1) (i), (ii)	442.433.
449.13(b)(1)(iii)	442.434.
449.13(b)(1) (iv)–(vi)	442.435.
449.13(b)(1)(vii)	442.436.
449.13(b)(1)(viii)–(x)	442.437.
449.13(b)(1)(xi) introductory paragraph and (A)–(C).	442.438 (a)–(e).
449.13(b)(1)(xi)(D) 1st sentence.	442.439(a).
449.13(b)(1)(xi)(D) 2d sentence.	442.438(f).
449.13(b)(1)(xi)(E)	442.439 (b), (c).
449.13(b)(1)(xii)	442.440.
449.13(b)(1)(xiii)	442.441 (b)–(d).
449.13(b)(2)	442.442.
449.13(b)(3)	442.443.
449.13(b)(4)	442.444.
449.13(b)(5)	442.445.
449.13(b)(6)(i)	442.447 (a) (1), (2), (4), (5), (b), (c).
449.13(b)(6)(ii)	442.448.
449.13(b)(6) (iii), (iv)	442.449 (a), (b).
449.13(b)(6) (v), (vi)	442.450(a) (2), (3).
449.13(b)(6) (vii), (viii)	442.451(a).
449.13(b)(6)(ix)	442.452.
449.13(b)(6)(x)	442.451(b).
449.13(b)(6)(xi)	442.450 (a)(4), (b), (c).
449.13(b)(6)(xii)	442.453.

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Old section	New section
449.13(b)(6)(xiii)	442.449(c).
449.13(c)(1)	442.454.
449.13(c)(1)(i)	442.455.
449.13(c)(1)(ii)	442.456.
449.13(c)(2)(i)	442.457.
449.13(c)(2)(ii)	442.458.
449.13(c)(2)(iii)	442.459.
449.13(c)(2)(iv)	442.460.
449.13(c)(2)(v)	442.461.
449.13(c)(2)(vi)	442.462.
449.13(c)(3)(i)	442.401, 442.463(a).
449.13(c)(3) (ii)–(v)	442.463 (b)–(e).
449.13(c)(10) (v), (vi)	442.491 (b), (c).
449.13(c)(11)(i)	442.494.
449.13(c)(11) (ii)–(vi)	442.495.
449.13(c)(12) (i), (ii)	442.496.
449.13(c)(12) (iii), (iv)	442.497.
449.13(c)(12) (v), (vi)	442.498.
449.13(d)(1) (i)–(iii)	442.499.
449.13(d)(2)(i)	442.500.
449.13(d)(2) (ii), (iii)	442.501 (a), (b).
449.13(d)(2)(iv)	442.424(c), 442.501(c).
449.13(d)(3)	442.502.
449.13(d)(4)	442.503.
449.13(d)(5)	442.504.
449.13(e)	442.416.
449.13(f)(1)(i)	442.505.
449.13(f)(1) (ii), (iii)	442.506.
449.13(f)(1)(iv)	442.511.
449.13(f)(1)(v)	442.510.
449.13(f)(2)	442.512.
449.13(g)(1)	442.513.
449.13(g)(2)	442.514.
449.13(g)(3)	442.515.
449.13(g)(4)	442.516.
449.13(h)(1)	442.401.
449.13(h)(2)	442.409(a)(4), 442.410 (a)(1), (c).
449.13(h)(3)	Unnecessary.
449.13(h)(4)	442.409 (a) (1), (2), (b).
449.13(h) (5)–(9)	442.401.
449.13(h)(10)	442.441(a).
449.20	431.51.
449.31	447.10.
449.32	447.25.
449.13(c)(3)(vi)	442.411(a), 442.464.
449.13(c)(4)(i)	442.465.
449.13(c)(4) (ii), (iii)	442.466(a)–(c).
449.13(c)(4)(iv) introductory paragraph, 1st sentence.	442.466(d).
449.13(c)(4)(iv) introductory paragraph, 2d sentence, and (A)–(C).	442.467(a).
449.13(c)(4)(v)	442.468.
449.13(c)(4)(vi)	442.467(b).
449.13(c)(4)(vii) 1st and 2d sentences.	442.469.
449.13(c)(4)(vii) 3d sentence.	442.467(c).
449.13(c)(4)(vii) 4th and 5th sentences.	442.470.
449.13(c)(4) (viii), (ix)	442.471.
449.13(c)(4) (x), (xi)	442.472.
449.13(c)(4) (xii)–(xiv)	442.473.
449.13(c)(5) (i), (ii)	442.474 (a), (c), (e).
449.13(c)(5) (iii), (iv)	442.475.
449.13(c)(5)(v)	442.477.
449.13(c)(5) (vi), (vii)	442.476.
449.13(c)(5)(viii)	442.474(d).
449.13(c)(6) (i), (ii)	442.478.
449.13(c)(6)(iii)	442.479.
449.13(c)(6) (iv), (v)	442.480.
449.13(c)(7)(i) 1st sentence.	442.483(a).
449.13(c)(7)(i) 2d sentence, (ii), (iii).	442.482.
449.13(c)(7) (iv)–(vi)	442.483 (b)–(d).
449.13(c)(7)(vii)	442.484(a).
449.13(c)(7)(viii)	442.485.
449.13(c)(7) (ix)–(xi)	442.484 (b)–(d).
449.13(c)(8) (i)–(iii)	442.486.
449.13(c)(8)(iv)	442.487.
449.13(c)(8) (v), (vi)	442.488.
449.13(c)(9)(i)	442.489(a).
449.13(c)(9) (ii)–(iv)	442.490 (b)–(d).
449.13(c)(9)(v)	442.489(b).

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Old section	New section
449.13(c)(9)(vi)	442.490(a).
449.13(c)(10)(i)	442.491(a).
449.13(c)(10)(ii)	442.492.
449.13(c)(10) (iii), (iv)	442.493.
449.33(a) introductory paragraph.	442.10, 442.100.
449.33(a)(1) introductory paragraph except words "(including hospitals)".	442.12(a), 442.101.
449.33(a)(1) introductory paragraph words "(including hospitals)".	Unnecessary.
449.33(a)(1)(i) words before "that the facility meets".	442.101(b).
449.33(a)(1)(i) words after "this chapter".	442.101(d), 442.200, 442.202, 442.253.
449.33(a)(1)(ii) words before "and in the case", except words "pursuant to section 1910 of the Act".	442.101(b)(2).
449.33(a)(1)(ii) words "pursuant to sec. 1910 of the Act".	442.1(a)(7).
449.33(a)(1)(ii) words after "title XVIII of the act".	442.202(c)(3).
449.33(a)(1)(iii) words before "except that", except words "pursuant to sec. 1905 of the Act".	442.101(b)(1), 442.200, 442.202 (b), (c).
449.33(a)(1)(iii) words "pursuant to sec. 1905 of the Act".	442.1(a)(6).
449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)".	442.12(a), 442.101(a), 442.250.
449.33(a)(2) introductory paragraph words "(including hospital and skilled nursing facilities)".	Unnecessary.
449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section" and paragraph (E).	442.112.
449.33(a)(2)(i) words "in acordance with paragraph (a)(4)(iii) of this section".	Redundant.
449.33(a)(2)(i)(E)	Redundant.
449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section", and paragraphs (A) (2) and (3) and (D).	442.113.
449.33(a)(2)(ii) words "in accordance with paragraph (a)(4)(iii)(A) of this section".	Redundant.
449.33(a)(2)(ii)(A)(2)	Obsolete.
449.33(a)(2)(ii)(A)(3)	442.115.
449.33(a)(2)(ii)(D)	Redundant.
449.33(a)(3)	455.104.
449.33(a)(4) (i) and (ii) introductory paragraph.	442.100, 442.101(d).
449.33(a)(4)(ii)	442.105.
449.33(a)(4)(iii) except last sentence.	442.111.
449.33(a)(4)(iii) last sentence.	442.110(a), 442.111(a).
449.33(a)(4)(iv) (A), (B) (1).	442.105 (c), (d).
449.33(a)(4)(iv)(B)(2)	Obsolete.
449.33(a)(4)(v)	442.101(e).
449.33(a)(5)	431.610(h).
449.33(a)(6) 1st sentence	442.12(a).

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Old section	New section
449.33(a)(6) 2d sentence, words before "and the effective date".	442.15(a).
449.33(a)(6) 2d sentence, words after "of one year".	442.12(b).
449.33(a)(6) 3d sentence, words before "except that".	442.12(c), 442.15(b).
449.33(a)(6) 3d sentence, words after "by the survey agency" and before "or may elect".	442.15(b).
449.33(a)(6) 3d sentence, words after "period of certification".	442.12(d).
449.33(a)(6) 4th sentence	442.16.
449.33(a) (7), (8)	Surplusage.
449.33(a)(9)	442.20.
449.33(a)(10)	Redundant.
449.33(b)(1)	Redundant.
449.33(b)(2)	431.610(i).
449.40(a)(1) words before "and no reduction".	447.51.
449.40(a)(1) words after "under the plan".	447.53.
449.40(a)(2)	447.51.
449.40(a)(2) (i), (ii)	447.52.
449.40(a)(3) 1st and 2d sentences.	447.53.
449.40(a)(3) (i), (ii)	447.54.
449.40(a)(3)(iii)	447.55.
449.40(a)(3)(iv)	447.54.
449.40(a)(3)(v)	447.56.
449.40(a)(3)(vi) 1st sentence.	447.57.
449.40(a)(3)(vi) 2d sentence.	447.58.
449.40(b)	447.59.
449.41	431.625.
449.70	433.36.
449.82(a)	431.501.
449.82(b) (1)–(7)	431.502.
449.82(b)(8)	431.521.
449.82(b) (9)–(11)	431.502.
449.82(c)(1) (i)–(ix)	431.503.
449.82(c)(1)(x)	431.504.
449.82(c)(2)	431.512.
449.82(c)(3)	431.510.
449.82(c)(4)	431.511.
449.82(c)(5) introductory paragraph words before "a State plan for".	431.523–431.526, 431.557–431.560.
449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i).	431.527.
449.82(c)(5) introductory paragraph words after "and (2) of this section", and (i) 1st sentence.	431.568.
449.82(c)(5)(ii)	431.528, 431.569.
449.82(c)(5)(iii)	Redundant.
449.82(c)(5)(iv)	431.527, 431.568.
449.82(c)(5)(v) words before "which shall be".	431.529, 431.570.
449.82(c)(5)(v) words after "period of enrollment".	431.541, 431.581.
449.82(c)(5)(vi)	431.530, 431.571.
449.82(c)(5)(vii)	431.531, 431.572.
449.82(c)(5) (viii), (ix)	431.532, 431.573.
449.82(c)(5)(x)	431.533, 431.574.
449.82(c)(5)(xi)	431.534, 431.575.
449.82(c)(5)(xii)	431.535, 431.576.
449.82(c)(5)(xiii)	431.536, 431.577.
449.82(c)(5)(xiv)	431.537, 431.578.
449.82(c)(5)(xv)	431.565.
449.82(c)(5)(xvi)	431.522.
449.82(c)(6)(i)	431.540, 431.580.
449.82(c)(6)(ii)	431.541, 431.581.
449.83(c)(6)(iii)	431.542, 431.582.
449.82(c)(6)(iv)	431.543, 431.583.
449.82(c)(6)(v)	431.544, 431.584.
449.82(c)(6)(vi)	431.545, 431.585.
449.82(c)(6)(vii)	431.546, 431.586.

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Old section	New section
449.82(c)(6)(viii)	431.547.
449.82(c)(6)(ix)	431.548, 431.587.
449.82(c)(6)(x)	431.549, 431.588.
449.82(c)(6)(xi)	431.550, 431.589.
449.82(d)(1)	431.591.
449.82(d)(2)	431.592.
449.82(d)(3)	431.593.
449.82(d)(4) (i), (ii)	431.597.
449.82(d)(4)(iii)	431.594.
449.82(d)(4)(iv)	431.595.
449.82(d)(4)(v)	431.596.
449.100	Unnecessary.
449.101	441.201.
449.102	441.202.
449.103	441.203.
449.104	441.204.
449.105	441.205.
449.106	441.206.
449.107	441.207.
449.108	441.208.
449.109	Redundant with 45 CFR 205.50.

PART 450

Old section	New section
450.18 introductory paragraph.	456.2.
450.18(a) introductory paragraph.	456.3.
450.18(a)(1) introductory paragraph.	Unnecessary.
450.18(a)(1)(i)	456.22.
450.18(a)(1)(ii)	456.23.
450.18(a)(1)(iii)	456.3.
450.18(a)(1)(iv)	456.346, 456.347, 456.348.
450.18(a)(1)(v) except last sentence.	Unnecessary.
450.18(a)(1)(v) last sentence.	456.171, 456.271, 456.372.
450.18(a)(2)	456.60, 456.160, 456.260, 456.360.
450.18(a)(3) (i) and (iii)	456.80.
450.18(a)(3)(ii)	456.80, 456.180, 456.280, 456.380.
450.18(a)(3)(iv)	456.280, 456.281.
450.18(a)(4)	456.3.
450.18(a)(5)	456.3.
450.18(b)	456.4.
450.18(c)	456.5.
450.18(d) words before "and will perform".	456.6.
450.18(d) words after "of this chapter".	Redundant.
450.18(e)	Redundant.
450.18(f)	Obsolete.
450.19(a) Introductory paragraph first two words after caption and words after "intermediate care facility".	456.101.
450.19(a) first word, "mental Hospital," and words after "intermediate care facility" and before "which meets".	456.201(a).
450.19(a) first word and words after "mental hospital" except "and intermediate care".	456.301.
450.19(a) first word, words after "skilled nursing facility and" and 450.19(a)(4) introductory paragraph words after "Christian Science Sanatoriums.".	456.401.
450.19(a) introductory paragraph words after "* * * review plan * * *".	456.201(b).
450.19(a)(1) introductory paragraph.	456.102.

PART 450—Continued

Old section	New section
450.19(a)(1)(i)	456.113.
450.19(a)(1)(ii) introductory paragraph.	456.105.
450.19(a)(1)(ii)	456.106.
450.19(a)(1)(iii)(A)	456.129.
450.19(a)(1)(iii)(B)	456.142.
450.19(a)(1)(iii)(C)	456.129 and 456.134.
450.19(a)(1)(iv)	456.129 and 456.134.
450.19(a)(1)(v)	456.105.
450.19(a)(1)(vi)	456.112.
450.19(a)(1)(vii)	456.111.
450.19(a)(1)(viii) introductory paragraph words before "within one working day".	456.121.
450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical note.	456.125.
450.19(a)(1)(viii) parenthetical note.	456.127.
450.19(a)(1)(viii) introductory paragraph words after "of such application".	456.123.
450.19(a)(1)(viii)(A)	456.126.
450.19(a)(1)(viii)(B) 1st and 2d sentences except words after "criteria and" and before "are applied".	456.122.
450.19(a)(1)(viii)(B) 1st and 2d sentences.	456.123.
450.19(a)(1)(viii)(B) 3d sentence.	Obsolete.
450.19(a)(1)(viii) (C), (D), (E) words before "and written notification" and (F) words before "written notification thereof".	456.123.
450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary.".	456.124.
450.19(a)(1)(ix)	456.128.
450.19(a)(1)(ix) words before "and recorded".	456.123.
450.19(a)(1)(ix) words after "shall be assigned" and before "based on the patient's".	456.111.
450.19(a)(1)(x) words before "by the Group".	456.135.
450.19(a)(1)(x) introductory paragraph.	456.135.
450.19(a)(1)(x)(A)	456.137.
450.19(a)(1)(x)(B)	456.135.
450.19(a)(1)(x)(C) 1st and 2d sentences except words after "criteria and" and before "are applied".	456.132.
450.19(a)(1)(x)(C) 1st and 2d sentences.	456.135.
450.19(a)(1)(x)(C) 3d sentence.	Obsolete.
450.19(a)(1)(x)(D) words before "in accordance with".	456.135.
450.19(a)(1)(x)(D) words after "shall be determined".	456.133.
450.19(a)(1)(x) (E), (F), (G) words before "and written notification" and (H) words before "written notification".	456.135.

PART 450—Continued

Old section	New section
450.19(a)(1)(x) (G) words after "shall be considered final" and (H) words after "has not been justified".	456.136.
450.19(a)(1)(xi)(A) first 2 sentences.	456.141.
450.19(a)(1)(xi)(A) 3d and 4th sentences.	456.143.
450.19(a)(1)(xi)(A) 5th sentence.	456.145.
450.19(a)(1)(xi)(A) 6th sentence.	456.144.
450.19(a)(1)(xi)(B)	456.142.
450.19(a)(1)(xii)	456.142.
450.19(a)(2) introductory paragraph.	456.201(b).
450.19(a)(2)(i)	456.213.
450.19(a)(2)(ii) introductory paragraph.	456.205(a) and (b).
450.19(a)(2)(ii)(A)	456.206(b).
450.19(a)(2)(ii)(B)	456.206(c).
450.19(a)(2)(iii)(A)	456.242(a).
450.19(a)(2)(iii)(B)	456.235(b).
450.19(a)(2)(iv)	456.235(a).
450.19(a)(2)(v)	456.205(c).
450.19(a)(2)(vi)	456.212.
450.19(a)(2)(vii)	456.211.
450.19(a)(2)(viii) words before "on or before a specified date".	456.231.
450.19(a)(2)(viii) words after "necessity of continued stay" and before 7th sentence.	456.233.
450.19(a)(2)(viii) 7th sentence.	456.234(b).
450.19(a)(2)(viii) 8th sentence.	456.211(e).
450.19(a)(2)(ix) introductory paragraph.	456.236(a).
450.19(a)(2)(ix)(A)	456.238.
450.19(a)(2)(ix)(B)	456.236(c).
450.19(a)(2)(ix)(C) 1st sentence.	456.232(a), 456.236(c).
450.19(a)(2)(ix)(C) 2d sentence.	456.232(b), 456.236(c).
450.19(a)(2)(ix)(C) 3d sentence.	Obsolete.
450.19(a)(2)(ix)(D) words before "in accordance with".	456.236(d).
450.19(a)(2)(ix)(D) first sentence words after "is appropriate and".	456.211(e).
450.19(a)(2)(ix)(D) words after "date assigned".	456.234 (a) and (c).
450.19(a)(2)(ix)(D) second sentence words before "in like manner".	456.236(b).
450.19(a)(2)(ix)(E)	456.236(e).
450.19(a)(2)(ix)(F)	456.236(f).
450.19(a)(2)(ix)(G) words before "and written notification".	456.236(g).
450.19(a)(2)(ix)(G) words after "considered final".	456.237.
450.19(a)(2)(ix)(H) words before "written notification".	456.236(h).
450.19(a)(2)(ix)(H) words after "mental hospital services".	456.237.
450.19(a)(2)(x) introductory words.	456.242(b).
450.19(a)(2)(x)(A) 1st sentence.	456.241(a).
450.19(a)(2)(x)(A) 2d sentence.	456.241.
450.19(a)(2)(x)(A) 3d and 4th sentences.	456.243.
450.19(a)(2)(x)(A) 5th sentence.	456.245.
450.19(a)(2)(x)(A) last sentence.	456.244.

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Old section	New section
450.19(a)(2)(x)(B)	456.242(b).
450.19(a)(2)(xi)	456.242(b).
450.19(a)(3) introductory paragraph.	456.302.
450.19(a)(3)(i)	456.313.
450.19(a)(3)(ii) introductory paragraph.	456.305 (a) and (b).
450.19(a)(3)(ii)(A)	456.306(b).
450.19(a)(3)(ii)(B)	456.306(c).
450.19(a)(3)(iii)(A)	456.342(a).
450.19(a)(3)(iii)(B)	456.335.
450.19(a)(3)(iv)	456.335.
450.19(a)(3)(v)	456.305(c).
450.19(a)(3)(vi)	456.312.
450.19(a)(3)(vii)	456.311.
450.19(a)(3)(viii) words before "on or before a specified date".	456.331.
450.19(a)(3)(viii) introductory paragraph.	456.333.
450.19(a)(3)(viii) introductory paragraph 2d sentence words before "is either".	456.311(e).
450.19(a)(3)(viii)(A) words before "but at least".	456.333.
450.19(a)(3)(viii)(A) words after "functional capabilities".	456.334(b).
450.19(a)(3)(viii)(B) words after "first 90 days".	456.334(b).
450.19(a)(3)(ix) introductory paragraph, (A) and (B) 1st and 2d sentences.	456.336 (a) and (c).
450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny".	456.332.
450.19(a)(3)(ix)(B) 3d and 4th sentence.	Obsolete.
450.19(a)(3)(ix)(C) words before "in accordance with".	456.336(d).
450.19(a)(3)(ix)(C) words after "date assigned".	456.334 (a) and (c).
450.19(a)(3)(ix)(C) after "is appropriate" and before "At the expiration".	456.311(e).
450.19(a)(3)(ix) last sentence words before "in like manner".	456.336(b).
450.19(a)(3)(ix)(D)	456.336(e).
450.19(a)(3)(ix)(E)	456.336(f).
450.19(a)(3)(ix)(F) words before "and written notification" and (G) words before "written notification".	456.336 (g) and (h).
450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date"; and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date".	456.337.
450.19(a)(3)(ix) (F) words after "shall be sent" except (1)-(4) and (G) words after "shall be made" except (1)-(4).	456.388.
450.19(a)(3)(x)(A) 1st and 2d sentences.	456.341.
450.19(a)(3)(x)(A) 3d and 4th sentences.	456.343.
450.19(a)(3)(x)(A) 5th sentence.	456.345.
450.19(a)(3)(x)(A) 6th sentence.	456.344.
450.19(a)(3)(x)(B)	456.342(b).
450.19(a)(3)(xi)	456.342(b).
450.19(a)(4) introductory paragraph parenthetical note.	456.351.
450.19(a)(4) 2d and 3d sentences except (i)-(vii).	456.401.
450.19(a)(4)(i)	456.413.
450.19(a)(4)(ii) 1st sentence except "and by whom".	456.405.
450.19(a)(4)(ii)(A) words after "How, when and".	456.406.
450.19(a)(4)(ii)(B)	456.407.
450.19(a)(4)(iii)	456.435.
450.19(a)(4)(iv)	456.412.
450.19(a)(4)(v)	456.411.
450.19(a)(4)(vi) words before "or more frequently" and words after "at the time of assessment".	456.431.
450.19(a)(4)(vi) 1st sentence words after "for continued stay".	456.433, 456.434.
450.19(a)(4)(vii) introductory paragraph.	456.436.
450.19(a)(4)(vii)(A)	456.436.
450.19(a)(4)(vii)(B)	456.436.
450.19(a)(4)(vii)(B) 2d sentence except words "and closer professional scrutiny".	456.432.
450.19(a)(4)(vii)(C) words before "in accordance with".	456.436, 456.411(e).
450.19(a)(4)(vii)(C) words after "date assigned".	456.434.
450.19(a)(4)(vii)(C) 2d sentence words before "in like manner".	456.436.
450.19(a)(4)(vii)(D)	456.436.
450.19(a)(4)(vii)(E)	456.436.
450.19(a)(4)(vii)(F) words before "and written notification" and (G) words before "written notification".	456.436.
450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "to: (1)" and (G) words after "intermediate care facility services" to words before "to: (1)".	456.438.
450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "not later than" and words after "final determination"; and (G) words after "intermediate care facility services" and before "not later than" and words after "such final determination".	456.437.
450.19(b) 1st sentence	456.505.
450.19(b) 2d sentence	456.507.
450.19(b) 3d sentence	456.507.
450.19(b) 4th sentence	456.508.
450.19(b) 5th sentence	Redundant.
450.19(b) 6th sentence	456.506.
450.19(b) 7th sentence	456.506.
450.19(b) 8th sentence	456.506.
450.19(c)(1)(i)	456.520.
450.19(c)(1)(ii)	Redundant.
450.19(c)(2)	456.521(a)(1).
450.19(c)(3)	456.522(f).
450.19(c)(4)	456.522(j).
450.19(c)(5) 1st sentence	456.521(a)(2).
450.19(c)(5) 2d sentence	456.523(a).
450.19(c)(6)	456.521(b).
450.19(c)(7)	456.522.
450.19(c)(7)(i)	456.522(a).
450.19(c)(7)(ii)	456.522(b).
450.19(c)(7)(iii)	456.522(c).
450.19(c)(7)(iv)	456.522(g).
450.19(c)(7)(v)	456.522(d).
450.19(c)(7)(vi)	456.522(e).
450.19(c)(7)(vii)	456.522(h).
450.19(c)(7)(viii)	456.522(f).
450.19(c)(7)(ix)	456.522(k).
450.19(c)(8) 1st sentence words before "upon receipt" and after "of this section,".	456.524(b).
450.19(c)(8) words after "agency shall," and before "promptly notify".	456.524(a)(1).
450.19(c)(8) 2d sentence	456.523(b).
450.19(c)(9) 1st sentence	456.524(a)(2).
450.19(c)(9)2d sentence	456.525.
450.19(c)(9) 3d sentence	456.525.
450.20(a)	Redundant.
450.20(b)	Obsolete.
450.20(c) 1st sentence	456.501.
450.20(c) 2d, 3d, and 4th sentences.	456.506.
450.21	431.107.
450.23(a)	456.2.
450.23(a)(1) 1st and 2d sentences.	456.170, 456.180, 456.270, 456.280.
450.23(a)(1) 3d sentence	456.481, 456.482.
450.23(a)(1) 4th sentence	Redundant.
450.23(a)(1)(i)	456.170, 456.270.
450.23(a)(1)(ii)	456.180, 456.280.
450.23(a)(1)(iii)	456.281.
450.23(a)(1)(iv)	456.170, 456.181, 456.270.
450.23(a)(2) (i) and (ii)	456.602.
450.23(a)(2)(iii)	456.603.
450.23(a)(3)(ii)	456.604.
450.23(a)(3)(i)	456.605.
450.23(a0(3)(iii)	456.606, 456.607.
450.23(a)(3)(iv)	Redundant.
450.23(a)(3)(v) 1st and 2d sentence.	456.608.
450.23(a)(3)(v), 3d sentence.	456.609.
450.23(a)(3)(v)(A)-(F)	456.610.
450.23(a)(4)(i)	456.611.
450.23(a)(4)(ii)	456.612.
450.23(a)(4)(iii)	456.613.
450.23(b)	456.614
450.23(c)	Unnecessary.
450.24(a) Introductory paragraph except parenthetical note.	456.2.
450.24(a) Parenthetical note.	456.601.
450.24(a)(1) Introductory paragraph.	456.370.
450.24(a)(1)(i) (A)-(C) 1st sentence.	456.370.
450.24(a)(1)(i)(C) 2d sentence.	456.371.
450.24(a)(1)(ii)	456.380.
450.24(a)(1)(iii)	456.381.
450.24(a)(2)(i)	456.602.
450.24(a)(2(ii)	456.603.
450.24(a)(3)(i)	456.605.
450.24(a)(3)(ii)	456.604.
450.24(a)(3)(iii)	456.606.
450.24(a)(3)(iv)	456.607.
450.24(a)(3)(v) 1st to 3d sentences.	456.608.
450.24(a)(3)(v) 4th sentence.	456.609.
450.24(a)(3)(v) (A)-(G)	456.610.
450.24(a)(4)(i)	456.611.
450.24(a)(4)(ii)	456.612.
450.24(a)(4)(iii)	456.613.
450.24(b)	Unnecessary.
450.24(c)	456.614.
450.30(a)(1)	447.201.
450.30(a)(2) (i), (ii)	447.261.
450.30(a)(2)(iii)	Redundant
450.30(a)(3) introductory paragraph, words before "as determined".	447.273.

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Old section	New section
450.30(a)(3) introductory paragraph, words after "cost-related basis".	447.221.
450.30(a)(3)(i)(A)	447.275.
450.30(a)(3)(i)(B)	447.274.
450.30(a)(3)(i)(C)	447.276.
450.30(a)(3)(i)(D)	447.274.
450.30(a)(3)(i)(E)	447.277.
450.30(a)(3)(i)(F)	447.277.
450.30(a)(3)(ii) introductory paragraph, 1st sentence, words before "and shall describe".	Surplusage.
450.30(a)(3)(ii) introductory paragraph, 1st sentence words after "of this section".	447.290.
450.30(a)(3)(ii) introductory paragraph, 2d sentence.	447.294.
450.30(a)(3)(ii)(A)	447.294.
450.30(a)(3)(ii)(B)	447.291.
450.30(a)(3)(ii)(C)	Surplusage.
450.30(a)(3)(ii)(D)	447.292.
450.30(a)(3)(ii)(E) words before "which audits shall".	447.293.
450.30(a)(3)(ii)(E) words after "exceptional profiles".	Surplusage.
450.30(a)(3)(ii)(F)	447.295.
450.30(a)(3)(ii)(G)	447.296.
450.30(a)(3)(iii) introductory paragraph.	447.278.
450.30(a)(3)(iii)(A)	447.279.
450.30(a)(3)(iii)(B)	447.281.
450.30(a)(3)(iii)(C)	447.282, 447.283.
450.30(a)(3)(iii)(D)	447.284.
450.30(a)(3)(iv) introductory paragraph.	447.301.
450.30(a)(3)(iv)(A)	447.302.
450.30(a)(3)(iv)(B)	447.303.
450.30(a)(3)(iv)(C)	447.304.
450.30(a)(3)(iv)(D)	447.305.
450.30(a)(3)(iv)(E)	447.306.
450.30(a)(3)(iv)(F)	447.307.
450.30(a)(3)(v)	447.311.
450.30(a)(3)(vi)	447.272.
450.30(a)(4)	447.252.
450.30(a)(5)	447.202.
450.30(a)(6)	447.203.
450.30(a)(7)	447.204.
450.30(a)(8)	447.15.
450.30(a)(9)	Obsolete.
450.30(b) introductory paragraph, 1st sentence.	447.252.
450.30(b) introductory paragraph, 2d sentence.	Surplusage.
450.30(b) introductory paragraph, 3d sentence.	447.252.
450.30(b) introductory paragraph, last sentence.	447.40.
450.30(b)(1) words before "or, in the case of".	447.262.
450.30(b)(1) words after "for such services".	Redundant.
450.30(b)(2) introductory paragraph.	447.331.
450.30(b)(2)(i)	447.333.
450.30(b)(2)(ii)	447.332.
450.30(b)(2)(iii)	447.332.
450.30(b)(2)(iv) 1st sentence.	447.334.
450.30(b)(2)(iv) 2d sentence.	Redundant.
450.30(b)(3) (i), (ii)(A)	447.341.
450.30(b)(3)(ii)(B)	Obsolete.
450.30(b)(3)(ii)(C)	447.341.
450.30(b)(4)	447.351.
450.30(b)(5)	447.321, 447.322.
450.30(b)(6)(i)	447.316.
450.30(b)(6)(ii)	447.315.
450.30(b)(6)(iii)	447.315.

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Old section	New section
450.30(b)(7)	447.361.
450.30(c)	447.252.
450.30(d)(1)	447.252.
450.30(d)(2)	447.40.
450.31	433.135.
450.41	431.105.
450.70	431.115.
450.71	433.37.
450.80(a)(1)	455.12, 455.13, 455.11.
450.80(a)(2)	455.13.
450.80(a)(3)	455.13.
450.80(a)(4)	455.17.
450.80(a)(5)(i)	455.18.
450.80(a)(5)(ii)	455.19.
450.80(a)(5)(iii)	455.18.
450.80(a)(6)	455.20.
450.80(a)(7)	455.22.
450.80(a)(8)	455.21.
450.80(b)(1)	455.14.
450.80(b)(2)	455.15, 455.16.
450.80(c)	455.23.
450.80(d)	455.21.
450.90(a)	433.111.
450.90(b)(1)	433.112.
450.90(b)(2)	433.113.
450.90(b)(3)	433.114.
450.90(b)(4)	Unnecessary.
450.100 except (c), words "excluding * * * Massachusetts".	431.610.
450.100(c), words "excluding * * * Massachusetts".	442.12.
450.210	447.35.
450.220	447.30.

PART 451

Old section	New section
451.10	431.615.

PART 452

Old section	New section
452.10(a)	431.700.
452.10(b)(1)	431.701, 431.704.
452.10(b)(2)	431.701.
452.10(b)(3)	431.706.
452.10(b)(4)	431.701.
452.10(b)(5)	431.701.
452.10(b)(6)	431.710.
452.10(b)(7)	431.714.
452.10(c)	431.702.
452.10(c)(1)	431.703.
452.10(c)(2)	431.705.
452.10(c)(2)(i)	431.707.
452.10(c)(2)(ii)	431.708.
452.10(c)(2)(iii) 1st sentence.	431.709.
452.10(c)(2)(iii) 2d and 3d sentences.	431.710.
452.10(c)(2)(iv)	431.711.
452.10(c)(2)(v)	431.712.
452.10(c)(2)(vi)	431.713.
452.10(d)	431.714.
452.10(e)	431.715.

This list includes only new sections based on regulations existing before recodification. Sections containing new material that is introductory or explanatory have not been included.

PART 431

New section	Old section
431.12	446.10.
431.51	449.20.
431.52	448.40(a).
431.53	449.10(a)(5)(ii).
431.105	450.41.
431.107	450.21.
431.110	449.10(a)(11).
431.115	450.70.
431.501	449.82(a).
431.502	449.82(b) (1)-(7), (9)-(11).
431.503	449.82(c)(1) (i)-(ix).
431.504	449.82(c)(1)(x).
431.510	449.82(c)(3).
431.511	449.82(c)(4).
431.512	449.82(c)(2).
431.521	449.82(b)(8).
431.522	449.82(c)(5)(xvi).
431.523-431.526	449.82(c)(5) introductory paragraph words before "a State plan for".
431.527	449.82(c)(5) introductory paragraph words after "and (2) of this section", and (i), (iv).
431.528	449.82(c)(5)(ii).
431.529	449.82(c)(5)(v) words before "which shall be".
431.530	449.82(c)(5)(vi).
431.531	449.82(c)(5)(vii).
431.532	449.82(c)(5)(viii), (ix).
431.533	449.82(c)(5)(x).
431.534	449.82(c)(5)(xi).
431.535	449.82(c)(5)(xii).
431.536	449.82(c)(5)(xiii).
431.537	449.82(c)(5)(xiv).
431.540	449.82(c)(6)(i).
431.541	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii).
431.542	449.82(c)(6)(iii).
431.543	449.82(c)(6)(iv).
431.544	449.82(c)(6)(v).
431.545	449.82(c)(6)(vi).
431.546	449.82(c)(6)(vii).
431.547	449.82(c)(6)(viii).
431.548	449.82(c)(6)(ix).
431.549	449.82(c)(6)(x).
431.550	449.82(c)(6)(xi).
431.557-431.560	449.82(c)(5) words before "a State plan for".
431.565	449.82(c)(5)(xv).
431.568	449.82(c)(5) introductory paragraph words after "and (2) of this section" and (i) 1st sentence, (iv).
431.569	449.82(c)(5)(ii).
431.570	449.82(c)(5)(v) words before "which shall be".
431.571	449.82(c)(5)(vi).
431.572	449.82(c)(5)(vii).
431.573	449.82(c)(5) (viii) and (ix).
431.574	449.82(c)(5)(x).
431.575	449.82(c)(5)(xi).
431.576	449.82(c)(5)(xii).
431.577	449.82(c)(5)(xiii).
431.578	449.82(c)(5)(xiv).
431.580	449.82(c)(6)(i).
431.581	449.82(c)(5)(v) words after "period of enrollment" and (6)(ii).
431.582	449.82(c)(6)(iii).
431.583	449.82(c)(6)(iv).
431.584	449.82(c)(6)(v).
431.585	449.82(c)(6)(vi).
431.586	449.82(c)(6)(vii).
431.587	449.82(c)(6)(ix).
431.588	449.82(c)(6)(x).
431.589	449.82(c)(6)(xi).
431.591	449.82(d)(1).
431.592	449.82(d)(2).
431.593	449.82(d)(3).
431.594	449.82(d)(4)(iii).
431.595	449.82(d)(4)(iv).
431.596	449.82(d)(4)(v).

PART 431—Continued

New section	Old section
431.597	449.82(d)(4)(i), (ii).
431.610	450.100.
431.615	451.10.
431.625	449.41.
431.700	452.10(a).
431.701	452.10(b) (1), (2), (4), (5).
431.702	452.10(c).
431.703	452.10(c)(1).
431.704	452.10(b)(1).
431.705	452.10(c)(2).
431.706	452.10(b)(3).
431.707	452.10(c)(2)(i).
431.708	452.10(c)(2)(ii).
431.709	452.10(c)(2)(iii) 1st sentence.
431.710	452.10(b)(6) and 452.10(c)(2)(iii) 2d and 3d sentences.
431.711	452.10(c)(2)(iv).
431.712	452.10(c)(2)(v).
431.713	452.10(c)(2)(vi).
431.714	452.10(b)(7) and 452.10(d).
431.715	452.10(e).

PART 432

New section	Old section
432.2	446.151.
432.10	446.160.
432.30	446.170.
432.31	446.165.
432.32	446.166.
432.50	446.175.
432.55	446.180.
432.60	446.185.

PART 433

New section	Old section
433.36	449.70.
433.37	450.71.
433.111	450.90(a).
433.112	450.90(b)(1).
433.113	450.90(b)(2).
433.114	450.90(b)(3).
433.135	450.31.

PART 435

New section	Old section
435.2	"Note" at beginning of 448.1.
435.10	448.1(b) 1st sentence. 448.1(c) 1st sentence. 448.1(e). 448.3(a)(1)(ii)(c), 1st sentence.
435.110	448.1(b)(1)(i). 448.10(b)(1)(i).
435.111	448.1(b)(1)(ii).
435.112	448.1(b)(1)(iii).
435.113	448.1(b)(3)(i).
435.114	448.1(b)(3)(ii).
435.120	448.1(b)(2)(i).
435.121	448.1(b)(2)(iii).
435.122	448.1(b)(3)(i).
435.130	448.1(b)(2)(iv).
435.131	448.1(b)(2)(v).
435.132	448.1(b)(2)(vi).
435.133	448.1(b)(2)(vii).
435.134	448.1(b)(3)(ii).
435.135	448.1(b)(2)(viii).
435.200	448.1(c) 1st sentence.
435.210	448.1(c)(1).
435.211	448.1(c)(2).
435.220	448.1(c)(6).
435.221	448.1(c)(5).

PART 435—Continued

New section	Old section
435.222	448.1(c)(4).
435.223(a)	448.1(c)(3).
435.230	448.1(b)(2)(ii). 448.2(d).
435.231	448.2(e).
435.301	448.1(a)(2)(i). 448.1(d)(1).
435.310	448.1(d)(1).
435.320	448.1(d)(1).
435.321	448.1(a)(1)(ii)(A) and (d)(1).
435.325	445.1(d)(2).
435.401	448.2 (a) and (c).
435.402	448.50.
435.403	448.40(b).
435.404	448.3(b)(6).
435.510	448.1(c) and 448.2(b)(1).
435.520	448.30(a), (b) (2), (3).
435.530	448.70(a)(1).
435.531	448.70(a) (2), (3), (b), (c)(1).
435.540	448.80(a)(1).
435.541	448.80(a)(2), (b), (c)(1).
435.602	448.3(b)(1)(iii).
435.603	448.3(b)(1)(ii).
435.711	448.3(a)(1)(i).
435.712	448.3(b)(1)(i), (5) (i)–(iii).
435.721	448.2(e), 448.3(a)(1)(ii)(A) and (B), (b)(2)(iii).
435.722	448.2(e).
435.723	448.3(b)(1)(i), (2).
435.724	448.3(b)(1)(i), (3).
435.725	448.3(b) (7), (8).
435.731	448.3(b)(7), (b)(9).
435.732	448.1 (a)(1)(ii), (b)(2)(iii), 448.3(b) (8), (9).
435.733	448.3(b)(8).
435.734	448.3(b)(4).
435.740	448.1(a)(3).
435.811	448.3(b)(2)(iv), (3)(v), (5)(v), (c)(1)(i). 448.4(b)(4)(ii).
435.812	448.3(c)(1)(ii)(B), (iii).
435.813	448.3(b)(7).
435.814	448.3(b)(2)(iv), (3)(v), (5)(iv), (c)(1)(ii)(B), (iii).
435.815	448.3(b)(2)(iv), (7).
435.816	448.3(b)(3)(v), (5)(iv)(c)(1)(ii)(A), 448.4(b)(4)(ii)(B).
435.821	448.3(b)(5).
435.822	448.3 (b) (2), (3).
435.823	448.3(b)(4).
435.831	448.1(a)(2)(ii), (b)(2)(iv), (3)(v), (5)(iv), (c)(2), (3), (4).
435.832	448.3(b) (7), (8).
435.840	448.3(c)(1)(iv).
435.841	448.3(c)(1)(iv).
435.845	448.3(c) (3), (4).
435.1001	448.4(a), 448.70(c)(2), and 448.80(c)(2).
435.1002	448.4(b) (1), (5), (8).
435.1003	448.4(b)(7).
435.1004	448.4(b)(6).
435.1005	448.4(b)(3), (c).
435.1006	448.3(a)(1)(ii)(B)(2) 448.4(b)(3), (c).
435.1007	448.4(b)(4), (c).
435.1008	448.4(b)(2), 448.60(a)(1)–(3)(i), (iv).
435.1009	448.60(a)(3)(ii), (iii)(b) (1)–(11), 449.10(d)(1).
435.1010	448.4(d).
435.1011	448.4(e).

PART 436

New section	Old section
436.10	448.10(b), 448.21(a).
436.110	448.10(b)(1)(i).
436.111	448.10(b)(1)(iii).
436.112	448.10(b)(3).

PART 436—Continued

New section	Old section
436.115	448.10(b)(1)(ii).
436.116(a)	448.10(b)(4).
436.210	448.10(b)(2)(i).
436.211	448.10(b)(2)(ii).
436.212	448.10(b)(2)(iii).
436.220	448.10(b)(2)(vi).
436.221	448.10(b)(2)(v).
436.222	448.10(b)(2)(iv).
436.230	448.11.
436.301	448.10(b)(5) 1st sentence.
436.310	448.10(b)(5) 1st sentence.
436.320	448.10(b)(5) 1st sentence.
436.330	448.10(b)(5) 1st sentence.
436.401	448.10(c)(1), (3)(4).
436.402	448.50.
436.403	448.40.
436.404	448.21(a)(2)(vi).
436.510	448.10(c)(3).
436.520	448.30.
436.530	448.70.
436.531	448.70.
436.540	448.80.
436.541	448.80.
436.602	448.21(a)(2)(ii).
436.603	448.21(a)(2)(i)(c) 1st sentence words after "applicant or recipient" and 2d sentence.
436.711	448.21(a)(1)(i), (a)(2)(iv), (v).
436.811	448.21(a)(3)(i)(A).
436.812	448.21(a)(3)(i)(B); 448.21(a)(2)(v).
436.813	448.21(a)(3)(1)(C).
436.821	448.21(a)(2)(iv), (v).
436.831	448.21(a)(3)(ii), (iii), (iv).
436.832	448.21(a)(3)(i)(C) except 1st and 2d sentence.
436.840	448.21(a)(3)(i)(D).
436.845	448.21(a)(3)(iii), (iv).
436.1001	448.10(d).
436.1002(a)	448.10(d)(1).
436.1002(b)	448.10(d)(3).
436.1003	448.10(d)(4).
436.1004(a)	448.10(d)(2) paragraph after (vi).
436.1004(b)	448.60(a)(3)(i).
436.1004(c)	448.60(a)(3)(iv).
436.1005	448.60.

PART 440

New section	Old section
440.2	449.10(b) introductory paragraph: 449.10(d)(1).
440.10	449.10(b)(1).
440.20	449.10(b)(2).
440.30	449.10(b)(3).
440.40	449.10(b)(4)(i)(A), (C), (ii) 1st sentence.
440.50	449.10(b)(5).
440.60	449.10(b)(6).
440.70	449.10(b)(7).
440.80	449.10(b)(8).
440.90	449.10(b)(9).
440.100	449.10(b)(10).
440.110	449.10(b)(11).
440.120	449.10(b)(12).
440.130	449.10(b)(13).
440.140	449.10(b)(14).
440.150	449.10(b)(15)(i)(A) 1st sentence, (B), (iii).
440.160	449.10(b)(16) introductory paragraph.
440.170	449.10(b)(17).
440.210	449.10(a)(1).
440.220	449.10(a)(2).
440.230	449.10(a)(5)(i).
440.240	449.10(a)(6) introductory paragraph and (7).
440.250	449.10(a)(6)(i)-(vii).
440.260	449.10(a)(8).

PART 441

New section	Old section
441.11	449.10(d)(3).
441.13	449.10(c) (1), (2).
441.15	449.10(a)(4).
441.20	449.10(a)(9).
441.30	449.10(a)(10).
441.40	449.10(c)(4).
441.51	449.10(a)(3) introductory paragraph.
441.52	449.10(b)(4)(ii) 2d and 3d sentences.
441.53	449.10(a)(3)(iv).
441.54	449.10(a)(3)(i).
441.55	449.10(a)(3)(ii).
441.56	449.10(a)(3)(iii).
441.151	449.10(b)(16)(i), (ii).
441.152	449.10(b)(16)(iii) introductory paragraph.
441.153	449.10(b)(16)(iii)(A) words after "of these regulations", and (C)-(E).
441.154	449.10(b)(16)(iii)(A) words before "and for whom".
441.155	449.10(b)(16)(iv)(B).
441.156	449.10(b)(16)(iv)(C).
441.181	449.10(c)(5)(ii) (A)-(G).
441.182	449.10(c)(5) (i) and (ii) introductory paragraph.
441.201	449.101.
441.202	449.102.
441.203	449.103.
441.204	449.104.
441.205	449.105.
441.206	449.106.
441.207	449.107.
441.208	449.108.

PART 442

New section	Old section
442.1	449.33(a)(1)(ii) words "pursuant to section 1910 of the Act" and (iii) words "pursuant to section 1905 of the Act".
442.10	449.33(a) introductory paragraph.
442.12	449.33(a)(1) execpt words "(including hospitals)," (6) 2d sentence, words after "of one year", 3d sentence, words before "except that" and after "period of certification" 450.100(c).
442.15	449.33(a)(6) 2d sentence words before "and the effective date" 3d sentence, words before "or may elect".
442.16	449.33(a)(6) 4th sentence.
442.20	449.33(a)(9).
442.30	449.10(b)(4)(i)(C).
442.100	449.33(a)(4) (i) and (ii) introductory paragraph.

PART 442—Continued

New section	Old section
442.101	449.33(a)(1) introductory paragraph execpt words "(including hospitals)," (i),(ii) words before "and in the case" except words "pursuant to section 1910 of the Act", (iii) words before "and in the case" except words "Pursuant to section 1905 of the Act", (2) introductory, paragraph except words "(including hospitals and skilled nursing facilities)", (4)(i), (ii) introductory paragraph, (v).
442.105	449.33(a)(4)(ii), (iv)(A), (B) (*1*).
442.110	449.33(a)(4)(iii) last sentence.
442.111	449.33(a)(4)(iii) last sentence.
442.112	449.33(a)(2)(i) except words "in accordance with paragraph (a)(4)(iii) of this section".
442.113	449.33(a)(2)(ii) except words "in accordance with paragraph (a)(4)(iii)(A) of this section", and paragraphs (A) (*2*) and (*3*) and (D).
442.115	449.33(a)(2)(ii)(A)(*3*).
442.200	449.33(a)(1)(iii) words before "except that", except words "pursuant to section 1905 of the Act".
442.201	449.10(a)(11), (b)(4)(i)(B).
442.202	449.33(a)(1)(i) words after "this chapter," (ii) words after "title XVIII of the Act," (iii) words before "except that" except words "pursuant to section 1905 of the Act".
442.250	449.33(a)(2) introductory paragraph except words "(including hospitals and skilled nursing facilities)".
442.251	449.10(a)(11)(b)(15)(i)(A).
442.252	449.10(b)(15)(i)(C).
442.253	449.33(a)(1)(i) words after "this chapter".
442.254	449.10(b)(15)(ii).
442.300	449.12(a) introductory paragraph.
442.301	449.12(a)(1).
442.302	449.12(a)(1)(i) 1st sentence.
442.303	449.12(b)(1).
442.304	449.12(b)(2).
442.305	449.12(a)(1)(ii)(A).
442.306	449.12(a)(1)(ii)(A)(*1*)(i).
442.307	449.12(a)(1)(ii)(A)(*1*) (ii), (iii).
442.308	449.12(a)(1)(ii)(A)(*2*).
442.309	449.12(a)(1)(ii)(A)(*3*).
442.310	449.12(a)(ii)(A)(*4*).
442.311	449.12(a)(1)(ii)(B).
442.312	449.12(a)(1)(ii)(C).
442.313	449.12(a)(1) (iv), (v).
442.314	449.12(a)(1)(vi).
442.315	449.12(a)(1)(vii).
442.316	449.12(a)(2).
442.317	449.12(a)(3).
442.318	449.12(a)(4)(i) (A)-(E), (ii), (iii).
442.319	449.12(a)(4)(i)(C).
442.320	449.12(a)(1)(iii).

PART 442—Continued

New section	Old section
442.321	449.12(a)(5) introductory paragraph, (iii).
442.322	449.12(a)(5)(i).
442.323	449.12(a)(5)(ii), undesignated paragraph following paragraph (iii).
442.324	449.12(a)(6)(i) 1st sentence, (iv).
442.325	449.12(a)(6)(i) 2d and 3d sentences and paragraph (a).
442.326	449.12(a)(6)(i) 2d sentence, (iii).
442.327	449.12(a)(6)(ii).
442.328	449.12(a)(6) (v), (vi).
442.329	449.12(a)(6) (vii), (viii).
442.330	449.12(a)(6)(ix).
442.331	449.12(a)(7) (i), (vi), (vii).
442.332	449.12(a)(7) (ii)-(iv).
442.333	449.12(a)(8)(i).
442.334	449.12(a)(8)(ii).
442.335	449.12(a)(8)(iii).
442.336	449.12(a)(8)(v).
442.337	449.12(a)(8) (iv), (vi).
442.338	449.12(a)(9) introductory paragraph.
442.339	449.12(a)(9)(i) introductory paragraph and (A)-(C).
442.340	449.12(a)(9)(ii).
442.341	449.12(a)(9)(iv).
442.342	449.12(a)(9)(v).
442.343	449.12(b)(3).
442.344	449.12(b)(4).
442.345	449.12(b)(5)
442.346	449.12(b)(6).
442.400	449.13 introductory paragaph, 1st sentence, words after "July 18, 1977".
442.401	449.12(c)(3) introductory paragraph, 2d sentence, and paragraphs (i)-(ix), 449.13(c)(3)(i), (h)(1), (5)-(9).
442.402	449.13(a)(1)(i).
442.403	449.13(a)(1)(ii).
442.404	449.12(a)(1)(ii)(B).
442.405	449.12(a)(1)(ii)(C).
442.406	449.12(a)(1)(iii), 449.13(a)(1)(iii).
442.407	449.13(a)(1)(iv).
442.408	449.13(a)(1)(v).
442.409	449.13(a)(1) (vi), (vii)(h)(2), (4).
442.410	449.13(c)(2),449.13(a)(1)(viii), (h)(2).
442.411	449.12(c)(3) introductory paragraph, 1st sentence, 449.13(c)(3)(vi).
442.412	449.13(a)(1)(ix).
442.413	449.13(a)(1)(x).
442.414	449.13(a)(1)(xi).
442.415	449.12(a)(1)(vii).
442.416	449.13(e).
442.417	449.12(a)(3)(i).
442.418	449.12(c)(1), 449.13(a)(2)(i) introductory paragraph, 1st sentence (iii), (iv).
442.419	449.13(a)(2)(ii).
442.420	449.13(a)(2)(i) introductory paragraph, 2d. sentence, and (A), (B).
442.421	449.13(a)(2)(v).
442.422	449.13(a)(2)(vi).
442.423	449.13(a)(2)(vii).
442.424	449.13(a)(2) (viii), (ix), (d)(2)(iv).
442.425	449.12(a)(2), 449.13(a) (viii), (x).
442.426	449.13(a)(2) (xi), (xii).
442.427	449.13(a)(3) (ii), (vi), (xi).
442.428	449.13(a)(3) (iii), (iv).

PART 442—Continued

New section	Old section
442.429	449.13(a)(3)(v).
442.430	449.13(a)(3)(vii).
442.431	449.13(a)(3)(viii).
442.432	449.13(a)(3) (ix), (x).
442.433	449.13(b)(1) (i), (ii).
442.434	449.13(b)(1)(iii).
442.435	449.13(b)(1) (iv)–(vi).
442.436	449.13(b)(1)(vii).
442.437	449.13(b)(1) (viii)–(x).
442.438	449.13(b)(1)(xi) introductory paragraph, (A)–(C), (D) 2d sentence.
442.439	449.13(b)(1)(xi)(D) 1st sentence, (E).
442.440	449.13(b)(1)(xii).
442.441	449.13(b)(1)(xiii), (h)(10).
442.442	449.13(b)(2).
442.443	449.13(b)(3).
442.444	449.13(b)(4).
442.445	449.13(b)(5).
442.446	449.12(a)(6)(i).
442.447	449.12(a)(6)(i), 449.13(b)(6)(i).
442.448	449.12(a)(6)(i), 449.13(b)(6)(ii).
442.449	449.13(b)(6) (iii), (iv), (xiii).
442.450	449.13(b)(6) (v), (vi), (xi).
442.451	449.13(b)(6) (vii), (viii), (x).
442.452	449.13(b)(6)(ix).
442.453	449.13(b)(6)(xii).
442.454	449.13(c)(1).
442.455	449.13(c)(1)(i).
442.456	449.13(c)(1)(ii).
442.457	449.13(c)(2)(i).
442.458	449.13(c)(2)(ii).
442.459	449.13(c)(2)(iii).
442.460	449.13(c)(2)(iv).
442.461	449.13(c)(2)(v).
442.462	449.13(c)(2)(vi).
442.463	449.13(c)(3) (i)–(v).
442.464	449.13(c)(3)(vi).
442.465	449.13(c)(4)(i).
442.466	449.13(c)(4) (ii), (iii), (iv) introductory paragraph, 1st sentence.
442.467	449.13(c)(4)(iv) introductory paragraph, 2d sentence, (A)–(C),(vi),(vii) 3d sentence.
442.468	449.13(c)(4)(v).
442.469	449.13(c)(4)(vii) 1st and 2d sentences.
442.470	449.13(c)(4)(vii) 4th and 5th sentences.
442.471	449.13(c)(4) (viii), (ix).
442.472	449.13(c)(4) (x), (xi).
442.473	449.13(c)(4) (xii)–(xiv).
442.474	449.12(a)(9) introductory paragraph, 449.13(c)(5) (i), (ii), (viii).
442.475	449.13(c)(5) (iii), (iv).
442.476	449.12(a)(3)(ii), 449.13(c)(5) (vi), (vii).
442.477	449.13(c)(5)(v).
442.478	449.12(a)(9)(v) words before "and, in the case of," 449.13(c)(6) (i), (ii).
442.479	449.13(c)(6)(iii).
442.480	449.13(c)(6) (iv), (v).
442.481	449.12(a)(9) (i)–(iv).
442.482	449.13(c)(7)(i) 2d sentence, (ii), (iii).
442.483	449.13(c)(7)(i) 1st sentence, (iv)–(vi).
442.484	449.13(c)(7)(vii), (ix)–(xi).
442.485	449.13(c)(7)(viii).
442.486	449.13(c)(8) (i)–(iii).
442.487	449.13(c)(8)(iv).
442.488	449.13(c)(8) (v), (vi).
442.489	449.13(c)(9) (i), (v).
442.490	449.13(c)(9) (ii)–(iv), (vi).
442.491	449.13(c)(10) (i), (v), (vi).

PART 442—Continued

New section	Old section
442.492	449.13(c)(10)(ii).
442.493	449.13(c)(10) (iii), (iv).
442.494	449.13(c)(11)(i).
442.495	449.13(c)(11) (ii)–(vi).
442.496	449.13(c)(12) (i), (ii).
442.497	449.13(c)(12) (iii), (iv).
442.498	449.13(c)(12) (v), (vi).
442.499	449.13(d)(1) (i)–(iii).
442.500	449.13(d)(2)(i).
442.501	449.13(d)(2) (ii)–(iv).
442.502	449.13(d)(3).
442.503	449.13(d)(4).
442.504	449.13(d)(5).
442.505	449.13(f)(1)(i).
442.506	449.13(f)(1) (ii), (iii).
442.507	449.12(a)(5) introductory paragraph, (iii).
442.508	449.12(a)(5)(i).
442.509	449.12(a)(5) (ii), undesignated paragraph following paragraph (iii).
442.510	449.13(f)(1)(v).
442.511	449.12(a)(6)(ix), 449.13(f)(1)(iv).
442.512	449.13(f)(2).
442.513	449.13(g)(1).
442.514	449.13(g)(2).
442.515	449.13(g)(3).
442.516	449.13(g)(4).

PART 447

New section	Old section
447.10	449.31.
447.15	450.30(a)(8).
447.25	449.32.
447.30	450.220.
447.35	450.210.
447.40	450.30(b) introductory paragraph, last sentence, and (d)(1).
447.51	449.40(a)(1) words before "and no deduction" and (2) introductory paragraph.
447.52	449.40(a)(2) (i), (ii).
447.53	449.40(a)(1) words after "under the plan" and (3) introductory paragraph.
447.54	449.40(a)(3) (i), (ii), (iv).
447.55	449.40(a)(3)(iii).
447.56	449.40(a)(3)(v).
447.57	449.40(a)(3)(vi) 1st sentence.
447.58	449.40(a)(3)(vi) 2d sentence.
447.59	449.40(b).
447.201	450.30(a)(1).
447.202	450.30(a)(5).
447.203	450.30(a)(6).
447.204	450.30(a)(7).
447.251	450.30(a)(3) introductory paragraph, words after "cost-related basis".
447.252	450.30(b) introductory paragraph, except 2d and last sentences, (C), (d)(1).
447.261	450.30(a)(2) except (iii).
447.262	450.30(b)(1) except words after "for such services".
447.272	450.30(a)(3)(vi).
447.273	450.30(a)(3) introductory paragraph, words before "as determined".
447.274	450.30(a)(3)(i)(B), (D).
447.275	450.30(a)(3)(i)(A).
447.276	450.30(a)(3)(i)(C).
447.277	450.30(a)(3)(i)(E), (F).
447.279	450.30(a)(3)(iii)(A).
447.281	450.30(a)(3)(iii)(B).

PART 447—Continued

New section	Old section
447.282	450.30(a)(3)(iii)(C).
447.283	450.30(a)(3)(iii)(C).
447.284	450.30(a)(3)(iii)(D).
447.290	450.30(a)(3)(ii) introductory paragraph, words after "of this section".
447.291	450.30(a)(3)(ii)(B).
447.292	450.30(a)(3)(ii)(D).
447.293	450.30(a)(3)(ii)(E) except words after "exceptional profiles".
447.294	450.30(a)(3)(ii) introductory paragraph, 2d sentence and (A).
447.295	450.30(a)(3)(ii)(F).
447.296	450.30(a)(3)(ii)(G).
447.302	450.30(a)(3)(iv)(A).
447.303	450.30(a)(3)(iv)(B).
447.304	450.30(a)(3)(iv)(C)
447.305	450.30(a)(3)(iv)(D)
447.306	450.30(a)(3)(iv)(E)
447.307	450.30(a)(3)(iv)(F)
447.311	450.30(a)(3)(v).
447.315	450.30(b)(6) (ii), (iii).
447.316	450.30(b)(6)(i).
447.321	450.30(b)(5).
447.322	450.30(b)(5).
447.341	450.30(b)(3) except (ii)(B).
447.351	450.30(b)(4).

PART 455

New section	Old section
455.11	450.80(a)(1) last sentence.
455.12	450.80(a)(1) 1st sentence.
455.13	450.80(a)(1) 1st sentence, (2), (3).
455.14	450.80(b)(1).
455.15, 455.16	450.80(b)(2).
455.17	450.80(a)(4).
455.18	450.80(a)(5) (i), (iii).
455.19	450.80(a)(5)(ii), (8).
455.20	450.80(a)(6).
455.21	450.80(d).
455.22	450.80(a)(7).
455.23	450.80(c).
455.104	449.33(a)(3).
455.300	450.310.

REDESIGNATION TABLE

PART 456—UTILIZATION CONTROL

New section	Old section
456.2	450.18 introductory paragraph, 450.23(a), 450.24(a) introductory paragraph except parenthetical note.
456.3	450.18(a), (iii), (4), (5).
456.4	450.18(b).
456.5	450.18(c).
456.6	450.18(d) words before "and will perform."
456.22	450.18(a)(1)(i).
456.23	450.18(a)(1)(ii).
456.60	450.18(a)(2).
456.80	450.18(a)(3) (i) and (iii).
456.101	450.19(a) first two words and words after "intermediate care facility."
456.102	450.19(a)(1) introductory paragraph.
456.105	450.19(a)(1)(ii) introductory paragraph and (v).

PART 456—Continued

New section	Old section
456.106 (b) and (c)	450.19(a)(1)(ii).
456.111	450.19(a)(1) (vii) and (ix) words after "admission is necessary" and before "based on the patient's."
456.112	450.19(a)(1)(vi).
456.113	450.19(a)(1)(i).
456.121	450.19(a)(1)(viii) introductory paragraph words before "within one working day."
456.122	450.19(a)(1)(viii)(B), 1st and 2d sentences except words after "criteria and" and before "are applied."
456.123	450.19(a)(1)(viii) introductory paragraph words after "of such application", (B) 1st and 2d sentences, (C), (D), (E) words before "and written notification", (F) words before "written notification thereof", and (ix) words before "is recorded."
456.124	450.19(a)(1)(viii)(E) words after "shall be considered final" and (F) words after "is not necessary."
456.125	450.19(a)(1)(viii) introductory paragraph words before "by the committee" except parenthetical notes.
456.126	450.19(a)(1)(viii)(A).
456.127	450.19(a)(1)(viii) parenthetical note.
456.128	450.19 (a)(1)(ix).
456.129	450.19(a)(1)(iii) (A) and (C), and (iv).
456.132	450.19(a)(1)(x)(C) 1st and 2d sentences except words after "criteria and" and before "are applied."
456.133	450.19(a)(1)(x)(D) words after "shall be determined."
456.134	450.19(a)(1) (iii)(C) and (iv).
456.135	450.19(a)(1)(x) (B), (C) words before "The single State agency", (D), (E), (F), (G) words before "and written notification", and (H) words before "written notification."
456.136	450.19(a)(1)(x)(G) words after "shall be considered final" and (H) words after "has not been justified."
456.137	450.19(a)(1)(x)(A).
456.141	450.19(a)(1)(xi).
456.142	450.19(a)(1)(iii)(B), (xi)(B), and (xii).
456.143	450.19(a)(1)(xi)(A) 3d and 4th sentences.
456.144	450.19(a)(1)(xi)(A) 6th sentence.
456.145	450.19(a)(1)(xi)(A) 5th sentence.
456.160	450.18(a)(2).
456.170	450.23(a)(1) introductory paragraph 1st and 2d sentences, (i) and (iv).
456.171	450.18(a)(1)(v) last sentence.

PART 456—Continued

New section	Old section
456.180	450.18(a)(3)(ii), 450.23(a)(1) introductory paragraph 1st and 2d sentences, (ii), and (iv).
456.201(a)	450.19(a) introductory paragraph 1st word, "mental hospital", words after "review plan" and (2) introductory paragraph.
456.205	450.19(a)(2)(ii) introductory paragraph and (v).
456.206 (b) and (c)	450.19(a)(2)(ii).
456.211	450.19(a)(2) (vii), (viii) last sentence and (ix)(D) 1st sentence words after "is appropriate and."
456.212	450.19(a)(2)(vi).
456.213	450.19(a)(2)(i).
456.231	450.19(a)(2)(viii) words before "on or before a specified date."
456.232	450.19(a)(2)(ix)(C) 1st sentence.
456.233	450.19(a)(2)(viii) words after "necessity of continued stay" and before "Subsequent reviews"; and last sentence.
456.234	450.19(a)(2)(viii) words after "30 days after admission." and before "The assigned review date", and (ix)(D) words after "date assigned."
456.235	450.19(a)(2) (iii) (B) and (iv).
456.236	450.19(a)(2)(ix) (B), (C) 1st and 2d sentences, (D)–(G) words before "and written notification", and (H) words before "written notification."
456.237	450.19(a)(2)(ix)(G) words after "considered final" and (H) words after "mental hospital services."
456.238	450.19(a)(2)(ix)(A).
456.241	450.19(a)(2)(x)(A) 1st and 2d sentence.
456.242	450.19(a)(2) (iii)(A), (x)(B), and (xi).
456.243	450.19(a)(2)(x)(A) 3d and 4th sentences.
456.244	450.19(a)(2)(x)(A) last sentence words before "and (B)."
456.245	450.19(a)(2)(x)(A) 5th sentence.
456.260	450.18(a)(2).
456.270	450.23(a)(1) introductory paragraph 1st and 2d sentences, (i) and (iv).
456.271	450.18(a)(1)(v) last sentence.
456.280	450.18(a)(3) (ii), (iv), 450.23(a)(1) introductory paragraph 1st and 2d sentences and (ii).
456.281	450.18(a)(3)(iv), 450.23(a)(1)(iii).
456.301	450.19(a) introductory paragraph except "hospital, mental hospital" and "intermediate care facility."
456.302	450.19(a)(3) introductory paragraph.

PART 456—Continued

New section	Old section
456.305	450.19(a)(3)(ii) introductory paragraph and (v).
456.306 (b) and (c)	450.19(a)(3)(ii) (A) and (B).
456.311	450.19(a)(3) (vii), (viii) introductory paragraph words after "such application" and before "and is either:"; and (ix)(C) words after "is appropriate" and before "At the expiration."
456.312	450.19(a)(3)(vi).
456.313	450.19(a)(3)(i).
456.331	450.19(a)(3)(viii) words before "on or before a specified date."
456.332	450.19(a)(3)(ix)(B) 2d sentence except words "and closer professional scrutiny."
456.333	450.19(a)(3)(viii)(A) words before "but at least."
456.334	450.19(a)(3)(viii)(A) words after "functional capabilities", (B), and (ix)(C) words after "date assigned."
456.335	450.19(a)(3)(iii)(B) and (iv).
456.336	450.19(a)(3)(ix) (A), (B) words before "The single State agency", (C), (D), (E), (F) words before "and written notification", and (G) words before "written notification."
456.337	450.19(a)(3)(ix)(F) words after "shall be considered final" and before "not later than" and words after "the assigned review date"; and (G) words after "nursing facility services" and before "not later than" and words after "assigned review date."
456.338	450.19(a)(3)(ix)(F) words after "shall be sent" except (*1*)–(*4*), and (G) words after "shall be made" except (*1*)–(*4*).
456.341	450.19(a)(3)(x)(A) 1st and 2d sentences.
456.342	450.19(a)(3)(iii)(A), (x)(B).
456.343	450.19(a)(3)(x)(A) 3d and 4th sentences.
456.344	450.19(a)(3)(x)(A) 6th sentence.
456.345	450.19(a)(3)(x)(A) 5th sentence.
456.346	450.18(a)(1)(iv).
456.347	450.18(a)(1)(iv).
456.348	450.18(a)(1)(iv).
456.360	450.18(a)(2).
456.370	450.24(a)(1)(i) (A)–(C) 1st sentence.
456.371	450.24(a)(1)(i)(C) 2d sentence.
456.372	450.18(a)(1)(v) last sentence.
456.380	450.18(a)(3)(ii), 450.24(a)(1)(ii).
456.381	450.24(a)(1)(iii).
456.401	450.19(a) introductory paragraph first word, words after "skilled nursing facility and", (4) 2d sentences except (i)–(vii).

PART 456—Continued

New section	Old section
456.402	450.19(a)(4) introductory paragraph parenthetical note.
456.405	450.19(a)(4)(ii)(A) 1st sentence except words "and by whom."
456.406	450.19(a)(4)(ii)(A) words after "How, when, and."
456.407	450.19(a)(4)(ii)(B).
456.411	450.19(a)(4) (v) and (vii)(C) words after "determined and" and before "in accordance with."
456.412	450.19(a)(4)(iv).
456.413	450.19(a)(4)(i).
456.431	450.19(a)(4)(vi) words before "or more frequently" and words after "time of assessment."
456.432	450.19(a)(4)(vii)(B) 2d sentence except words "and closer professional scrutiny."
456.433	450.19(a)(4)(vi) 1st sentence, words after "for continued stay."
456.434	450.19(a)(4) (vi) 1st sentence, words after "for continued stay" and (vii)(C) words after "date assigned."
456.435	450.19(a)(4)(iii).
456.436	450.19(a)(4)(vii) (A)–(F) words before "and written notification" and (G) words before "written notification."
456.437	450.19(a)(4)(vii)(F) words after "shall be considered final" to words before "not later than" and words after final determination, and (G) words after "intermediate care facility services" and before "not later than" and words after "such final determination."
456.438	450.19(a)(4)(vii)(F) words after "shall be considered final" except (*1*)–(*4*), and (G) words after "intermediate care facility services" except (*1*)–(*4*).
456.481	450.23(a)(1) 3d sentence.
456.482	450.23(a)(1) 3d sentence.
456.501	450.20(c) 1st sentence.
456.505	450.19(b) 1st sentence.
456.506	450.19(b) 6th to 8th sentences; and 450.20(c) 2d to 4th sentences.
456.507	450.19(b) 2d and 3d sentences.
456.508	450.19(b) 4th sentence.
456.520	450.19(c)(1)(i).
456.521	450.19(c)(2), (5) 1st sentence, and (6).
456.522	450.19(c) (3), (4), and (7).
456.523	450.19(c) (5) 2d sentence and (8) 2d sentence.
456.524	450.19(c) (8) 1st sentence and (9) 1st sentence.
456.525	450.19(c)(9) 2d and 3d sentences.
456.601	450.24(a) parenthetical note.
456.602	450.23(a)(2) (i) and (ii) and 450.24(a)(2)(i).
456.603	450.23(a)(2)(iii) and 450.24(a)(2)(ii).
456.604	450.23(a)(3)(ii) and 450.24(a)(3)(ii).

PART 456—Continued

New section	Old section
456.605	450.23(a)(3)(i) and 450.24(a)(3)(i).
456.606	450.23(a)(3)(iii) and 450.24(a)(3)(iii).
456.607	450.23(a)(3)(iii) and 450.24(a)(3)(iv).
456.608	450.23(a)(3)(v) 1st and 2d sentences and 450.24(a)(3)(v) 1st 3 sentences.
456.609	450.23(a)(3)(v) 3d sentence and 450.24(a)(3)(v) 4th sentence.
456.610	450.23(a)(3)(v) (A)–(F) and 450.24(a)(3)(v) (A)–(G).
456.611	450.23(a)(4)(i) and 450.24(a)(4)(i).
456.612	450.23(a)(4)(ii) and 450.24(a)(4)(ii).
456.613	450.23(a)(4)(iii) and 450.24(a)(4)(iii).
456.614	450.23(b) and 450.24(c).

42 CFR Chapter IV, Subchapter C, is revised by revoking parts 446, 448, 449, 450, 451, and 452 and adding new parts 430, 431, 432, 433, 435, 436, 440, 441, 442, 447, 455, and 456 as set forth below:

NOTE.—The regulations in subchapter C were reorganized and rewritten for clarity and simplicity, without policy change, effective October 1, 1978. Under HEW's Operation Common Sense, HCFA is publishing substantive changes in these regulations as proposed rulemaking.

PART 430—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

Subpart A—Introduction; Definitions

Sec.
430.0 Introduction to subchapter C.
430.1 Definitions.

AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—Introduction; Definitions

§ 430.0 Introduction to subchapter C.

(a) *Program description.* Title XIX of the Social Security Act, enacted in 1965, authorizes Federal grants to States for medical assistance to low-income persons who are age 65 or over, blind, disabled, or members of families with dependent children. The program is jointly financed by the Federal and State governments and administered by States. Within broad Federal rules, each State decides eligible groups, types and range of services, payment levels for services, and administrative and operating procedures. Payments for services are made directly by the State to the individuals or entities that furnish the services.

(b) *Federal regulations.* (1) The regulations in subchapter C set forth State plan requirements, standards, procedures, and conditions for obtaining Federal matching. Each part (or subpart or section) in the subchapter describes the specific statutory basis for the regulation. However, where the basis is the Secretary's general authority to issue regulations for any program under the Act (sec. 1102 of the Act), or his general authority to prescribe State plan requirements needed for proper and efficient administration of the plan (sec. 1902(a)(4)), those statutory provisions are simply cited without further description.

(2) Related HEW regulations applicable to State medicaid programs include the following in 45 CFR Subtitle A:

Part 16—Department Grant Appeals Process.
Part 19—Limitations on Payment or Reimbursement for Drugs.
Part 70—Standards for a Merit System of Personnel Administration.
Part 74—Administration of Grants.
Part 80—Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health, Education, and Welfare: Effectuation of Title VI of the Civil Rights Act of 1964.
Part 81—Practice and Procedure for Hearings Under 45 CFR Part 80.
Part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving or Benefiting From Federal Financial Assistance.

(3) Regulations in 45 CFR parts 201, 204, 205, 206, 208, and 213 also apply to the medicaid program, to the extent specified.

§ 430.1 Definitions.

In this subchapter, unless the context indicates otherwise—

"Act" means the Social Security Act, and titles referred to are titles of that Act;

"Administrator" means the Administrator, Health Care Financing Administration;

"Applicant" means an individual whose written application for medicaid has been submitted to the agency determining medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual;

"Bureau Director" means the Director of the Federal medicaid program with HCFA;

"Central office" means the headquarters office of HCFA;

"Federal financial participation" (FFP) means the Federal Government's share of a State's expenditures under the medicaid program;

"FMAP" means the Federal medical assistance percentage, which is used to calculate the amount of the Federal share of State expenditures for services;

"HEW" means the Department of Health, Education, and Welfare;

"HCFA" means the Health Care Financing Administration;

"Medicaid" means medical assistance provided under a State plan approved under title XIX of the Act;

"Medicaid agency" or "the agency" means the single State agency administering or supervising the administration of a State medicaid plan;

"Medicare" means the health insurance program for the aged and disabled under title XVIII of the Act;

"Provider" means any individual or entity furnishing medicaid services under a provider agreement with the medicaid agency;

"Recipient" means an individual who has been determined eligible for medicaid;

"Regional Administrator" means the Regional Administrator of HCFA;

"Regional Medicaid Director" means the Regional Medicaid Director of the federal medicaid program;

"Regional office" means one of the regional offices of HCFA;

"Secretary" means the Secretary of Health, Education, and Welfare;

"Services" means the types of medical assistance specified in sec. 1905(a)(1) through (17) of the Act;

"State" means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, and Guam;

"State plan" or "the plan" means a comprehensive written commitment by a medicaid agency, submitted under sec. 1902(a) of the Act, to administer or supervise the administration of a medicaid program in accordance with Federal requirements.

The masculine gender includes the feminine.

PART 431—STATE ORGANIZATION AND GENERAL ADMINISTRATION

Sec.
431.1 Purpose.

Subpart A—Single State Agency

431.12 Medical care advisory committee.

Subpart B—Administrative Requirements: General Program Services

431.51 Free choice of providers.
431.52 Payments for services furnished out of State.
431.53 Assurance of transportation.

Subpart C—Administrative Requirements: Provider Relations

431.105 Consultation to medical facilities.
431.107 Required provider agreement.
431.110 Participation by Indian Health Service facilities.
431.115 Disclosure of survey information and provider/contractor evaluations.

Subparts D–K [Reserved]

Subpart L—Contracts With Fiscal Agents, Health Care Project Grant Centers, Private Nonmedical Institutions, Health Insuring Organizations, Health Maintenace Organizations, and Prepaid Health Plans

GENERAL PROVISIONS

Sec.
431.501 Basis and purpose.
431.502 Definitions.

CONTRACT REQUIREMENTS

431.503 All contracts.
431.504 Subcontracts.

FISCAL AGENTS, PRIVATE NONMEDICAL INSTITUTIONS AND HEALTH INSURING ORGANIZATIONS

431.510 Fiscal agents.
431.511 Private nonmedical institutions.
431.512 Health insuring organizations.

HEALTH MAINTENACE ORGANIZATIONS

431.520 State plan requirements.
431.521 HMO's with provisional status.

HMO: CONTRACT REQUIREMENTS

431.522 Services and organization.
431.523 Premiums or subscription charges.
431.524 Risk.
431.525 Savings.
431.526 Reinsurance.
431.527 Coverage and enrollment.
431.528 Population.
431.529 Duration or enrollment period.
431.530 Termination of enrollment.
431.531 Choice of health professional.
431.532 Emergency medical services.
431.533 Grievance procedure.
431.534 Quality assurance system.
431.535 Marketing.
431.536 Health care information.
431.537 Medical recordkeeping system.

HMO: STATE AGENCY REQUIREMENTS

431.540 Proof of HMO capability.
431.541 Enrollment.
431.542 Provision of required services.
431.543 System of periodic medical audits.
431.544 Approval of marketing plans, procedures, and materials for enrollment.
431.545 Distribution of general information.
431.546 Payment to contractors.
431.547 Continued service to formerly enrolled recipients.
431.548 Computation of premium rates and subscription charges.
431.549 Monitoring procedures.
431.550 Contracts that provide fewer or more services than are available under the plan.

PREPAID HEALTH PLANS

431.555 State plan requirements.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—RISK BASIS

431.556 Risk-basis contracts; General requirements.
431.557 Premiums or subscription charges.
431.558 Amount of risk.
431.559 Savings.
431.560 Reinsurance.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—NONRISK BASIS

431.565 Nonrisk contract: Allowable payment for services.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—ALL CONTRACTS

Sec.
431.568 Coverage and enrollment.
431.569 Population.
431.570 Duration of enrollment period.
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Subpart P—Quality Control

431.800 Medicaid quality control (MQC) system.

AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

§ 431.1 Purpose.

This part establishes State plan requirements for the designation, organization, and general administrative activities of a State agency responsible for operating the State medicaid program, directly or through supervision of local administering agencies.

Subpart A—Single State Agency

§ 431.12 Medical care advisory committee.

(a) *Basis and purpose.* This section, based on sec. 1902(a)(4) of the Act, prescribes State plan requirements for establishment of a committee to advise the medicaid agency about health and medical care services.

(b) *State plan requirement.* A State plan must provide for a medical care advisory committee meeting the requirements of this section to advise the medicaid agency director about health and medical care services.

(c) *Appointment of members.* The agency director, or a higher State authority, must appoint members to the advisory committee on a rotating and continuous basis.

(d) *Committee membership.* The committee must include—

(1) Board-certified physicians and other representatives of the health professions who are familiar with the medical needs of low-income population groups and with the resources available and required for their care;

(2) Members of consumers' groups, including medicaid recipients, and consumer organizations such as labor unions, cooperatives, consumer-sponsored prepaid group practice plans, and others; and

(3) The director of the public welfare department or the public health department, whichever does not head the medicaid agency.

(e) *Committee participation.* The committee must have opportunity for participation in policy development and program administration, including furthering the participation of recipient members in the agency program.

(f) *Committee staff assistance and financial help.* The agency must provide the committee with—

(1) Staff assistance from the agency and independent technical assistance as needed to enable it to make effective recommendations; and

(2) Financial arrangements, if necessary, to make possible the participation of recipient members.

(g) *Federal financial participation.* FFP is available at 50 percent in expenditures for the committee's activities.

Subpart B—Administrative Requirements: General Program Services

§ 431.51 Free choice of providers.

(a) This sec. implements section 1902(a)(23) of the Act, which provides that recipients may obtain services from any qualified medicaid provider.

(b) A State plan (except in Puerto Rico, the Virgin Islands, and Guam) must provide that any recipient may obtain medicaid services from any institution, agency, pharmacy, person, or organization that is qualified to perform the services, including an organization that provides these services or arranges for their availability on a prepayment basis.

(c) If the medicaid agency contracts on a prepayment basis with an organization that provides services additional to those offered under the State plan, the agency may restrict the provision of the additional services to recipients who live in the area served by the organization and wish to obtain services from it.

(d) Paragraph (b) of this section does not prohibit the agency from—

(1) Establishing the fees it will pay providers for medicaid services; or

(2) Setting reasonable standards relating to the qualifications of providers.

§ 431.52 Payments for services furnished out of State.

(a) *Basis and purpose.* This section implements section 1902(a)(16) of the Act, which authorizes the Secretary to prescribe State plan requirements for furnishing medicaid to State residents who are absent from the State.

(b) *Payment for services.* A State plan must provide that the State will furnish medicaid to a recipient who is a resident of the State while that recipient is in another State, to the same extent that medicaid is furnished to residents in the State, when—

(1) Medical services are needed because of a medical emergency;

(2) Medical services are needed because the recipient's health would be endangered if he were required to travel to his State of residence;

(3) The State determines, on the basis of the attending physician's medical advice, that the needed medical services, or necessary supplementary resources, are more readily available in the other State; or

(4) It is general practice for recipients in a particular locality to use medical resources in another State.

(c) *Cooperation among States.* The plan must provide that the State will establish procedures to facilitate the furnishing of medical services to individuals who are present in the State and are eligible for medicaid under another State's plan.

§ 431.53 Assurance of transportation.

A State plan must—

(a) Specify that the medicaid agency will assure necessary transportation for recipients to and from providers; and

(b) Describe the methods that will be used to meet this requirement.

(Sec. 1902(a)(4) of the Act.)

Subpart C—Administrative Requirements: Provider Relations

§ 431.105 Consultation to medical facilities.

(a) *Basis and purpose.* This section implements section 1902(a)(24) of the Act, which requires that the State plan provide for consultative services by State agencies to certain institutions furnishing medicaid services.

(b) *State plan requirements.* A State plan must provide that health agencies and other appropriate State agencies furnish consultative services to hospitals, nursing homes, home health agencies, clinics, and laboratories in order to assist these facilities to—

(1) Qualify for payments under the maternal and child health and crippled children's program (title V of the Act), medicaid or medicare;

(2) Establish and maintain fiscal records necessary for the proper and efficient administration of the Act; and

(3) Provide information needed to determine payments due under the Act for services furnished to recipients.

(c) *State plan option: Consultation to other facilities.* The plan may provide that health agencies and other appropriate State agencies furnish consultation to other types of facilities if those facilities are specified in the plan and provide medical care to individuals receiving services under the programs specified in paragraph (b) of this section.

§ 431.107 Required provider agreement.

(a) *Basis and purpose.* This section implements section 1902(a)(27) of the Act, which requires agreements between medicaid agencies and providers.

(b) *Agreements.* A State plan must provide for an agreement between the medicaid agency and each provider furnishing services under the plan in which the provider agrees to—

(1) Keep any records necessary to disclose the extent of services the provider furnishes to recipients; and

(2) Furnish the agency or the Secretary with any information they may request regarding payments claimed by the provider for furnishing services.

§ 431.110 Participation by Indian Health Service facilities.

(a) *Basis.* This section is based on section 1902(a)(4) of the Act, proper and efficient administration; 1902(a)(23), free choice of provider; and 1911, reimbursement of Indian Health Service facilities.

(b) *State plan requirements.* A State plan must provide that an Indian Health Service facility meeting State requirements for medicaid participation must be accepted as a medicaid provider on the same basis as any other qualified provider. However, when State licensure is normally required, the facility need not obtain a license but must meet all applicable standards for licensure. In determining whether a facility meets these standards, a medicaid agency or State licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 431.115 Disclosure of survey information and provider/contractor evaluations.

(a) *Basis and purpose.* This section implements—

(1) Section 1902(a)(36) of the Act, which requires a State plan to provide that the State survey agency will make publicly available the findings from surveys of health care facilities, laboratories, agencies, clinics, or organizations; and

(2) Section 1106(d) of the Act, which places certain restrictions on the medicaid agency's disclosure of contractor and provider evaluations.

(b) *Definition of State survey agency.* The State survey agency referred to in this section means the agency specified under section 1902(a)(9) of the Act as responsible for establishing and maintaining health standards for private or public institutions in which medicaid recipients may receive services.

(c) *State plan requirement.* A State plan must provide that the requirements of this section are met.

(d) *Disclosure procedure.* The medicaid agency must have a procedure for disclosing pertinent findings obtained from surveys made by the State survey agency to determine if a health care facility, laboratory, agency, clinic or health care organization meets the requirements for participation in the medicaid program.

(e) *Documents subject to disclosure. Documents subject to disclosure include—*

(1) Survey reports, except for Joint Commission on the Accreditation of Hospitals reports prohibited from disclosure under § 422.426(b)(2) of this chapter;

(2) Official notifications of findings based on survey reports:

(3) Pertinent parts of written documents furnished by the health care provider to the survey agency that relate to the reports and findings; and

(4) Information regarding ownership of a skilled nursing facility (as prescribed in § 405.1121(a) of this chapter) and of an intermediate care facility (as prescribed in § 455.104 of this subchapter).

(f) *Availability for inspection and copy of statements listing deficiencies.* The disclosure procedure must provide that the State survey agency will—

(1) Make statements of deficiencies based on the survey reports available for inspection and copying in both the public assistance office and the Social Security Administration district office serving the area where the provider is located; and

(2) Submit to the Regional Medicaid Director, through the medicaid agency, a plan for making those findings available in other public assistance offices in standard metropolitan statistical areas where this information would be helpful to persons likely to use the health care provider's services.

(g) *When documents must be made available.* The disclosure procedure must provide that the State survey agency will—

(1) Retain in the survey agency office and make available upon request survey reports and current and accurate ownership information; and

(2) Make available survey reports, findings, and deficiency statements immediately upon determining that a health care provider is eligible to begin or continue participation in the medicaid program, or within 90 days after completion of the survey, whichever occurs first.

(h) *Evaluation reports on providers and contractors.* (1) If the Secretary sends the following reports to the medicaid agency, the agency must meet the requirements of paragraphs (h) (2) and (3) of this section in releasing them:

(i) Individual contractor performance reviews and other formal performance evaluations of carriers, intermediaries, and State agencies, including the reports of followup reviews;

(ii) Comparative performance evaluations of those contractors, including comparisons of either overall performance or of any particular aspect of contractor operations; and

(iii) Program validation survey reports and other formal performance evaluations of providers, including the reports of followup reviews.

(2) The agency must not make the reports public until—

(i) The contractor or provider has had a reasonable opportunity, not to exceed 30 days, to comment on them; and

(ii) Those comments have been incorporated in the report.

(3) The agency must ensure that the reports contain no identification of individual patients, individual health care practitioners or other individuals.

Subparts D–K—[Reserved]

Subpart L—Contracts with Fiscal Agents, Health Care Project Grant Centers, Private Nonmedical Institutions, Health Insuring Organizations, Health Maintenance Organizations and Prepaid Health Plans

General Provisions

§ 431.501 Basis and purpose.

(a) This subpart is based on section 1902(a)(4) of the Act, which requires that the State plan provide methods of administration that the Secretary finds necessary for the proper and efficient operation of the plan.

(b) This subpart prescribes State plan requirements governing contracts with certain organizations for processing or paying claims or providing medical services.

§ 431.502 Definitions.

For purposes of this subpart—

"Contractor" means any of the following entities that contract with the medicaid agency, under the terms of this subpart, to process claims or to pay for or provide medical services under a State plan in return for a payment:

(1) A fiscal agent.

(2) A health care project grant center.

(3) A private nonmedical institution.

(4) A health insuring organization.

(5) A health maintenance organization.

(6) A prepaid health plan.

"Enrolled recipient" means an individual who is eligible for medicaid and who enters into an agreement to receive services from a health maintenance organization or prepaid health plan that contracts with the agency under this subpart.

"Fiscal agent" means an entity that processes or pays vendor claims for the agency.

"Health care projects grant center" means an entity that—

(1) Is supported in whole or in part by Federal project grant financial assistance; and

(2) Provides or arranges for medical services to recipients.

"Health insuring organization" means an entity that—

(1) Pays for medical services provided to recipients in exchange for a premium or subscription charge paid by the agency; and

(2) Assumes an underwriting risk.

"Health maintenance organization (HMO)" means an entity determined by the Assistant Secretary for Health (Public Health Service) to meet the following requirements:

(1) It provides to its medicaid eligible enrollees as the "basic health services" required under sec. 1301 (b) and (c) of the Public Health Service Act—

(i) Inpatient hospital services;

(ii) Outpatient services;

(iii) Laboratory and X-ray services;

(iv) Family planning services and supplies;

(v) Physician services; and

(vi) Home health services for individuals entitled to those services under the medicaid State plan.

(2) It provides the services listed in paragraph (a) in the manner prescribed in sec. 1301(b) of the Public Health Service Act.

(3) It is organized and operated in the manner prescribed in sec. 1301(c) of the Public Health Service Act.

"Premium, subscription charge, or capitation fee" means the fee which is paid by the agency to a contractor for each recipient enrolled under a contract for the provision of medical services under the State plan, whether or not the recipient receives the services during the contract period.

"Prepaid health plan" means an entity that is not an HMO, and that provides medical services under contract with the medicaid agency to enrolled recipients on a prepaid capitation basis. This includes the providers identified in sec. 1903(m)(2)(B) (i), (ii), or (iii) of the act. That section refers to certain entities that received grants under the Public Health Service Act in the fiscal year ending June 30, 1976, certain rural primary health care entities, and certain entities that operated on a prepaid risk basis before 1970.

"Private nonmedical institution" means an entity that—

(1) Provides medical care through contracts or other arrangements with medical providers;

(2) Is paid on a prepaid capitation basis by the agency;

(3) Does not assume an underwriting risk; and

(4) Is not, as a matter of regular business, a prepaid health insuring organization or community health care center. Examples of private nonmedical institutions are child-care institutions and maternity homes.

"Risk" or "underwriting risk" means a significant chance of loss that—

(1) Is assumed by the contractor; and

(2) Arises because the cost of providing services may exceed the premiums, subscription charges, or capitation fees paid by the agency to the contractor during the contract period.

CONTRACT REQUIREMENTS

§ 431.503 All contracts.

A State plan must provide that contracts under this subpart—

(a) Are in writing;

(b) Specify the contract period;

(c) Specify the functions of the contractor;

(d) Identify the population covered by the contract;

(e) Specify any procedures for enrollment or reenrollment of the covered population;

(f) Specify the amount, duration, and scope of medical services to be provided or paid for;

(g) Provide that the agency and HEW may evaluate through inspection or other means, the quality, appropriateness and timeliness of services performed under the contract;

(h) Provide that the agency and HEW may audit and inspect any of the contractor's records that pertain to services performed and determination of amounts payable under the contract;

(i) Specify procedures and criteria for extending the contract;

(j) specify procedures and criteria for renegotiating the contract;

(k) Specify procedures and criteria for terminating the contract, including a requirement that the contractor promptly supply all information necessary for the reimbursement of any outstanding medicaid claims;

(l) Provide that the contractor maintains an appropriate record system for services to enrolled recipients;

(m) Provide that the records referred to in paragraph (l) are retained in accordance with the record retention requirements of 45 CFR part 74;

(n) Provide that the contractor safeguards information about recipients as required by 45 CFR 205.50;

(o) Specify any activities to be performed by the contractor that are related to third party liability requirements in § 433.135 of this subchapter;

(p) Specify which functions may be subcontracted; and

(q) Provide that any subcontracts meet the requirements of § 431.504.

§ 431.504 Subcontracts.

(a) Subcontracts must—

(1) Be in writing; and

(2) Fulfill the requirements of this subpart that are appropriate to the service or activity delegated under the subcontract.

(b) No subcontract terminates the legal responsibility of the contractor to the agency to assure that all activities under the contract are carried out.

FISCAL AGENTS, PRIVATE NONMEDICAL INSTITUTIONS, AND HEALTH INSURING ORGANIZATIONS

§ 431.510 Fiscal agents.

If the plan provides for contracts with fiscal agents, it must provide that the contracts—

(a) Meet the requirements of §§ 431.503 and 431.504;

(b) Include termination procedures that require the contractors to supply promptly all material necessary for continued operation of payment and related systems. This material includes—

(1) Computer programs;

(2) Data files;

(3) User and operation manuals, and other documentation;

(4) System and program documentation; and

(5) Training programs for medicaid agency staff, their agents or designated representatives in the operation and maintenance of the system;

(c) Offer to the State one or both of the following options, if the fiscal agent or the fiscal agent's subcontractor has a proprietary right to material specified in paragraph (b) of this section:

(1) Purchase of the material.

(2) Purchasing the use of the material through leasing or other means;

(d) State the amount to be paid to the contractor for performing the functions under the contract;

(e) State the basis for the amount to be paid to the contractor;

(f) State when payment is to be made to the contractor; and

(g) State that payment to providers must be made in accordance with part 477 of this subchapter.

§ 431.511 Private nonmedical institutions.

If the plan provides for contracts for prepayment of services from private nonmedical institutions, it must provide that the contracts—

(a) Meet the requirements of §§ 431.503 and 431.504;

(b) Specify a capitation fee based on the cost of the services provided, in accordance with the reimbursement requirements prescribed in part 447 of this subchapter; and

(c) Specify when the capitation amount must be paid.

§ 431.512 Health insuring organization.

(a) If a plan provides for contracts with health insuring organizations, it must provide that the contracts—

(1) Meet the requirements of §§ 431.503 and 431.504;

(2) Specify that the premium or subscription charge must not exceed the limits set forth under part 447 of this subchapter;

(3) Specify that, except as permitted under paragraph (b) of this section,

premiums or subscription charges paid on behalf of each recipient may not be renegotiated—

(i) During the contract period if the contract is for 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year;

(4) Specify that the premium or subscription charge must not include any amount for recoupment of any losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency;

(5) Specify that the contractor assumes at least part of the underwriting risk as follows:

(i) If the contractor assumes the full underwriting risk; payment of the premium or subscription charge to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract.

(ii) If the contractor assumes less than the full underwriting risk, the contract specifies the apportionment of the underwriting risk.

(6) Specify whether the contractor returns to the agency part of any savings remaining after allowable costs are deducted from the premium or subscription charge and, if savings are returned, the apportionment to the agency and the contractor;

(7) Specify the extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk;

(8) Specify the actuarial basis for computation of the premium or subscription charge.

(b) The premium or subscription charge may be renegotiated more often than annually for recipients who are not enrolled at the time of renegotiation or if the renegotiation is required by changes in Federal or State law.

HEALTH MAINTENANCE ORGANIZATIONS

§ 431.520 State plan requirements.

If the plan provides for contracts with HMO's, the plan must also provide that—

(a) Each contract with an HMO, including HMO's that have provisional status, meets the requirements of §§ 431.503 and 431.504 and the additional requirements of §§ 431.522 through 431.537; and

(b) The agency meets the requirements of §§ 431.540 through 431.550.

§ 431.521 HMO's with provisional status.

(a) The agency may determine that an entity is an HMO with provisional status if—

(1) More than 90 days have expired since the entity applied to the Public Health Service for HMO status; and

(2) The Assistant Secretary for Health has not determined whether the entity meets the definition of section 1903(m)(1)(A) of the Public Health Service Act.

(b) The provisional status remains in force until the earlier of the following:

(1) A final determination is made by the Assistant Secretary for Health.

(2) The contract expires.

HMO: CONTRACT REQUIREMENTS

§ 431.522 Services and organization.

(a) The contract must specify that the HMO—

(1) Provides services in the manner prescribed by section 1301(b) of the Public Health Service Act; and

(2) Is organized and operated as prescribed by section 1301(c) of the Public Health Service Act.

(b) For purposes of this subpart, HMO "basic health services" are those specified in paragraph (a) of "health maintenance organization" in § 431.502.

§ 431.523 Premiums or subscription charges.

(a) The contract must specify—

(1) The actuarial basis for computation of the premium or subscription charge;

(2) That the premium or subscription charge must not exceed the limits set forth under part 447 of this subchapter;

(3) That, except as permitted under paragraph (b) of this section, premiums or subscription charges paid on behalf of each enrolled recipient may not be renegotiated—

(i) During the contract period if the contract is for 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year; and

(4) That the premium or subscription charge must not include any amount for recoupment of any losses suffered by the contractor for risks assumed under the same contract or a prior contract with the agency.

(b) The premium or subscription charge may be renegotiated more often than annually for eligible recipients who are not enrolled at the time of the renegotiation or if the renegotiation is required by changes in Federal or State law.

§ 431.524 Risk.

The contract must specify that the contractor assumes at least part of the underwriting risk as follows:

(a) If the contractor assumes the full underwriting risk, payment of the premium or subscription charge to the contractor during the contract period constitutes full payment by the agency for the cost of medical services provided under the contract; and

(b) If the contractor assumes less than the full underwriting risk, the contract specifies the apportionment of the underwriting risk.

§ 431.525 Savings.

The contract must specify whether the contractor returns to the agency part of any savings remaining after allowable costs are deducted from the premium or subscription charge and, if savings are returned, the apportionment to the agency and the contractor.

§ 431.526 Reinsurance.

The contract must specify—

(a) The extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk; and

(b) That, if the contractor obtains reinsurance, he retains a substantial portion of the underwriting risk.

§ 431.527 Coverage and enrollment.

(a) The contract must specify an open enrollment period that meets the requirements of section 1301(d) of the Public Health Service Act, if the HMO—

(1) Has not incurred a financial deficit in the previous fiscal year; and

(2) Either has been in existence for at least 5 years, or has a minimum of 50,000 members.

(b) A contract with an HMO that does not meet the description of an HMO in paragraph (a) of this section must—

(1) Specify the period during which enrollment may be open;

(2) Provide that the contractor accepts individuals who are eligible to be covered under the contract—

(i) In the order in which they apply;

(ii) Without restrictions unless authorized by the Secretary; and

(iii) Up to the limits set in the contract with the State; and

(3) Provide that enrollment is voluntary.

§ 431.528 Population.

The contract must provide that—

(a) The contractor serves a population broadly representative of the various age, social, and income groups in the area served;

(b) Either less than 50 percent of the enrollees are medicare beneficiaries and medicaid recipients or the 50-percent requirement will be attained by October 8, 1979, or 3 years from the date that the contract is entered into, whichever is later;

(c) If the population does not meet the 50-percent requirement when the contract is entered into—

(1) The contractor will make continuous effort to progress toward compliance with paragraph (b) of this section; and

(2) The contractor will submit annual plans showing milestones for each year until the goal is achieved, in order to demonstrate progress to the Secretary's satisfaction.

§ 431.529 Duration of enrollment period.

The contract must specify the duration of the enrollment period.

§ 431.530 Termination of enrollment.

The contract—

(a) Must specify the reasons for which a recipient's enrollment may be terminated, which may not include an adverse change in a recipient's health;

(b) Must provide that a recipient who is enrolled has the right to terminate his enrollment without cause within 30 days of his enrollment;

(c) May allow termination by a recipient without cause at any time during the contract period; and

(d) Must provide that the agency approves each termination by the contractor.

§ 431.531 Choice of health professional.

The contract must allow each enrolled recipient to choose his health professional in the HMO to the extent possible and appropriate.

§ 431.532 Emergency medical services.

The contract must—

(a) Provide that all medical services that are covered under the contract and that are required on an emergency basis are available on a 24-hour basis, 7 days a week, either in the contractor's own facilities or through arrangements, approved by the agency, with another provider; and

(b) Provide for prompt payment by the contractor, under the upper limits prescribed in part 447 of this subchapter, for all services that are—

(1) Required by the contract;

(2) Furnished by providers that do not have arrangements with the contractor to provide the services; and

(3) Medically necessary to avoid endangering the recipient's health or causing him severe pain and discomfort that would occur if he had to use the contractor's facilities.

§ 431.533 Grievance procedure.

The contract must provide for an internal grievance procedure that—

(a) Is approved in writing by the agency;

(b) Provides for prompt resolution; and

(c) Assures the participation of individuals with authority to require corrective action.

§ 431.534 Quality assurance system.

The contract must provide for an internal quality assurance system that:

(a) Is consistent with the utilization control requirements of part 456 of this subchapter;

(b) Provides for review by appropriate health professionals of the process followed in providing health services;

(c) Provides for systematic data collection of performance and patient results;

(d) Provides for interpretation of this data to the practitioners; and

(e) Provides for making needed changes.

§ 431.535 Marketing.

The contract must provide that the HMO submits marketing plans, procedures, and materials to the agency for approval before using the plans.

§ 431.536 Health care information.

The contract must provide that the HMO advises enrolled recipients about the proper use of health care services and contributions they can make to the maintenance of their own health.

§ 431.537 Medical recordkeeping system.

The contract must provide for development of a medical recordkeeping system that—

(a) Collects all pertinent information relating to the medical management of each enrolled recipient; and

(b) Makes that information readily available to appropriate health professionals.

HMO: State Agency Requirements

§ 431.540 Proof of HMO capability.

The agency must obtain from each HMO contractor proof of—

(a) Financial responsibility, including proof of adequate protection against insolvency; and

(b) The contractor's ability to provide the services under the contract efficiently, effectively, and economically.

§ 431.541 Enrollment.

(a) The agency must determine that there have been adequate feasibility and planning studies made that show that enough people will enroll to insure the HMO's economic success.

(b) The agency must determine that the duration of the enrollment period is a sufficient amount of time to—

(1) Insure continuity of care; and

(2) Avoid excessive cost due to rapid turnover of enrolled recipients.

§ 431.542 Provision of required services.

The agency must obtain assurances from the HMO that—

(a) It provides the health services required by enrolled recipients as promptly as is appropriate; and

(b) The services meet the agency's quality standards.

§ 431.543 Periodic medical audits.

(a) The agency must establish a system of periodic medical audits to insure that the HMO provides quality and accessible health care to enrolled recipients.

(b) The system of periodic medical audits must—

(1) Provide for audits conducted at least once a year for each HMO contractor;

(2) Identify and collect management data for use by medical audit personnel; and

(3) Provide that the data includes—

(i) Reasons for enrollment and termination; and

(ii) Use of services.

§ 431.544 Approval of marketing plans, procedures, and materials for enrollment.

(a) The agency must provide for a system for approval of the HMO's marketing plans, procedures, and materials submitted under § 431.535.

(b) The requirements for approval must be in writing.

(c) The system must provide that the HMO contractor not engage in marketing practices that mislead, confuse, or defraud either recipients or the agency.

§ 431.545 Distribution of general information.

The agency must provide that—

(a) Appropriate health or social services agencies are used to distribute information regarding—

(1) Coverage;

(2) Location;

(3) Hours of services; and

(4) Enrollment and termination practices;

(b) The information is distributed to eligible recipients in the area serviced by the HMO contractor; and

(c) The information is accurate and presented in clear, readable, and concise form.

§ 431.546 Payment to contractors.

No payment may be made to providers other than the HMO for services provided to an enrolled recipient, if the services were available under the contract.

§ 431.547 Continued service to formerly enrolled recipients.

The agency must arrange for medicaid services without delay for any recipient whose enrollment is terminated, unless it is terminated because of ineligibility for medicaid.

§ 431.548 Computation of premium rates and subscription charges.

The agency must document the basis for computing the premium rates or subscription charges.

§ 431.549 Monitoring procedures.

The agency must have procedures to—

(a) Monitor enrollment and termination practices; and

(b) Insure proper implementation of the contractor's grievance procedures.

§ 431.550 Contracts that provide fewer or more services than are available under the plan.

(a) If the contract does not cover all services available under the plan, the agency must arrange for services not included to be available and accessible. This may be done by having the HMO refer enrolled recipients to other providers or by some other means.

(b) The contract may cover services in addition to those available under the plan. See § 440.250 for exception to the requirement for comparability of services to all recipients in the State.

PREPAID HEALTH PLANS

§ 431.555 State plan requirements.

If the plan provides for contracts with prepaid health plans, the State plan must also provide that—

(a) Each of those contracts meets the requirements of §§ 431.503, 431.504, and 431.568 through 431.578;

(b) In addition to the requirements of paragraph (a)—

(1) Each contract with a prepaid health plan that assumes an underwriting risk meets the requirements of §§ 431.556 through 431.560; and

(2) Each contract with a prepaid health plan that does not assume an underwriting risk meets the requirements of § 431.565; and

(c) The agency meets the requirements of §§ 431.580 through 431.589.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—RISK BASIS

§ 431.556 Risk-basis contracts: General requirements.

The contract with a prepaid health plan that assumes an underwriting risk must meet the requirements of §§ 431.557-431.560.

§ 431.557 Premiums or subscription charges.

(a) The contract must specify—

(1) The actuarial basis for computation of the premium or subscription charge;

(2) That the premium or subscription charge must not exceed the limits set forth under part 447 of this subchapter;

(3) That, except as permitted under paragraph (b) of this section, premiums, or subscription charges paid on behalf of each enrolled recipient may not be renegotiated—

(i) During the contract period if the contract is for 1 year or less; or

(ii) More often than annually if the contract period is for more than 1 year; and

(4) That the premium or subscription charge must not include any amount for recoupment of any losses suffered by the contractor for risks assumed under the same contract or a prior contract in the agency.

(b) The premium or subscription charge may be renegotiated more often than annually for eligible recipients who are not enrolled at the time of the renegotiation or if the renegotiation is required by changes in Federal or State law.

§ 431.558 Amount of risk.

The contract must specify—

(a) That, if the contractor assumes the full underwriting risk, payment of the premium or subscription charge to the contractor during the contract period constitutes full payment by the agency for the cost of the medical services provided under the contract; and

(b) The apportionment of the underwriting risk if the contractor assumes less than the full underwriting risk.

§ 431.559 Savings.

The contract must specify whether the contractor returns to the agency part of any savings remaining after allowable costs are deducted from the premium or subscription charge and, if savings are returned, the apportionment to the agency and the contractor.

§ 431.560 Reinsurance.

The contract must specify—

(a) The extent, if any, to which the contractor may obtain reinsurance of a portion of the underwriting risk; and

(b) That, if the contractor obtains reinsurance, he retains a substantial portion of the underwriting risk.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—RISK BASIS

§ 431.565 Nonrisk contract: Allowable payment for services.

(a) The contract with a prepaid health plan that does not assume any underwriting risk must provide that payment to the contractor does not exceed the amount that could be paid under part 447 for those specified provider services actually delivered by the contractor to enrolled recipients.

(b) For purposes of this section, "payment" includes any necessary retroactive adjustments.

PREPAID HEALTH PLANS: CONTRACT REQUIREMENTS—ALL CONTRACTS

§ 431.568 Coverage and enrollment.

The contract must—

(a) Specify the period during which enrollment may be open;

(b) Provide that the contractor accepts individuals who are eligible to be covered under the contract—

(1) In the order in which they apply;

(2) Without restrictions unless authorized by the Secretary; and

(3) Up to the limits set in the contract with the State; and

(c) Provide that enrollment is voluntary.

§ 431.569 Population.

The contract must provide that—

(a) The contractor serves a population broadly representative of the various age, social, and income groups in the area served;

(b) Either less than 50 percent of the enrollees are medicare beneficiaries and medicaid recipients or the 50-percent requirement will be attained by October 8, 1979, or 3 years from the date the contract is entered into, whichever is later;

(c) The contractor may apply to the Secretary for waiver of the requirements of paragraphs (a) and (b) of this section based on good cause.

§ 431.570 Duration of enrollment period.

The contract must specify the duration of the enrollment period.

§ 431.571 Termination of enrollment.

The contract—

(a) Must specify the reasons for which a recipient's enrollment may be terminated, which may not include adverse change in a recipient's health;

(b) Must provide that a recipient who is enrolled has the right to terminate his enrollment without cause within 30 days of enrollment;

(c) May allow termination by a recipient without cause at any time during the contract period; and

(d) Must provide that the agency approves each termination by the contractor.

§ 431.572 Choice of health professional.

The contract must allow each enrolled recipient to choose his health professional in the prepaid health plan to the extent possible and appropriate.

§ 431.573 Emergency medical services.

The contract must—

(a) Provide that all medical services that are covered under the contract and that are required on an emergency basis are available on a 24-hour basis, 7 days a week, either in the contractor's own facilities or through arrangements, approved by the agency, with another provider; and

(b) Provide for prompt payment by the contractor, under the limits set forth under part 447 of this subchapter for all services that are—

(1) Required by the contract;

(2) Furnished by providers that do not have arrangements with the contractor to provide the services; and

(3) Medically necessary to avoid endangering the recipient's health or causing him severe pain and discomfort that would occur if he had to use the contractor's facilities.

§ 431.574 Grievance procedure.

The contract must provide for an internal grievance procedure that—

(a) Is approved in writing by the agency;

(b) Provides for prompt resolution; and

(c) Assures the participation of individuals with authority to require corrective action.

§ 431.575 Quality assurance system.

The contract must provide for an internal quality assurance system that—

(a) Is consistent with the utilization control requirements of part 456 of this subchapter;

(b) Provides for review by appropriate health professionals of the process followed in providing health service;

(c) Provides for systematic data collection of performance and patient results;

(d) Provides for interpretation of this data to the practitioners; and

(e) Provides for making needed changes.

§ 431.576 Marketing.

The contract must provide that the prepaid health plan submits marketing plans, procedures, and materials to the agency for approval before using the plans.

§ 431.577 Health care information.

The contract must provide that the prepaid health plan advises enrolled recipients about the proper use of health care services and contributions they can make to the maintenance of their own health.

§ 431.578 Medical recordkeeping system.

The contract must provide for development of a medical recordkeeping system that—

(a) Collects all pertinent information relating to the medical management of each enrolled recipient; and

(b) Makes that information readily available to appropriate health professionals.

PREPAID HEALTH PLANS: STATE AGENCY REQUIREMENTS

§ 431.580 Proof of prepaid health plan capability.

The agency must obtain from each prepaid health plan contractor proof of—

(a) Financial responsibility, including proof of adequate protection against insolvency; and

(b) The contractor's ability to provide the services under the contract efficiently, effectively, and economically.

§ 431.581 Enrollment.

(a) The agency must determine that there have been adequate feasibility and planning studies made that show that enough people will enroll to insure the prepaid health plan's economic success.

(b) The agency must determine that the duration of the enrollment period is a sufficient amount of time to—

(1) Insure continuity of care; and

(2) Avoid excessive cost due to rapid turnover of enrolled recipients.

§ 431.582 Provision of required services.

The agency must obtain assurances from the prepaid health plan that—

(a) It provides the health services required by enrolled recipients as promptly as is appropriate; and

(b) The services meet the agency's quality standards.

§ 431.583 Periodic medical audits.

(a) The agency must establish a system of periodic medical audits to insure that the prepaid health plan provides quality and accessible health care to enrolled recipients.

(b) The system of periodic medical audits must—

(1) Provide for audits conducted at least once a year for each contractor;

(2) Identify and collect management data for use by medical audit personnel; and

(3) Provide that the data includes—

(i) Reasons for enrollment and termination; and

(ii) Use of services.

§ 431.584 Approval of marketing plans, procedures and materials for enrollment.

(a) The agency must provide for a system for approval of the prepaid health plan's marketing plans, procedures, and materials submitted under § 431.576.

(b) The requirements for approval must be in writing.

(c) The system must provide that the contractor not engage in marketing practices that mislead, confuse, or defraud either recipients or the agency.

§ 431.585 Distribution of general information.

The agency must provide that—

(a) Appropriate health or social services agencies are used to distribute information regarding—

(1) Coverage;

(2) Location;

(3) Hours of services; and

(4) Enrollment and termination practices;

(b) The information is distributed to eligible recipients in the area serviced by the contractor; and

(c) The information is accurate and presented in clear, readable, and concise form.

§ 431.586 Payment to contractors.

No payment may be made to providers other than the contractor for services provided to an enrolled recipient, if the services were available under the contract.

§ 431.587 Computation of premium rates and subscription charges.

The agency must document the basis for computing the premium rates or subscription charges.

§ 431.588 Monitoring procedures.

The agency must have procedures to—

(a) Monitor enrollment and termination practices; and

(b) Insure proper implementation of the contractor's grievance procedures.

§ 431.589 Contracts that provide fewer or more services than are available under the plan.

(a) If the contract does not cover all services available under the plan, the agency must arrange for services not included to be available and accessible. This may be done by having the prepaid health plan refer recipients to other providers or by some other means.

(b) The contract may cover services in addition to those available under the plan. See § 440.250 for exception to requirement for comparability of services to all recipients in the State.

FEDERAL FINANCIAL PARTICIPATION

§ 431.591 Availability of FFP.

(a) FFP is available in expenditures for payments to contractors only for the periods that the contract—

(1) Meets the requirements of this subpart;

(2) Meets the appropriate requirements of 45 CFR Part 74; and

(3) Is in effect.

(b) The Administrator may determine that a contract is not in effect for any period if the State fails to carry out the plan requirements of this subpart or if he determines that there was a substantial failure of either party to carry out the terms of the contract required by this subpart.

(c) A State is entitled upon request to receive a reconsideration, in accordance with section 1116(d) of the Act and 45 CFR Part 16, of a disallowance of FFP under this section.

§ 431.592 Availability of FFP for HMOs with provisional status.

(a) FFP is available in expenditures for payments to HMOs with provisional status regardless of the final determination on its qualifications to be an HMO.

(b) The Assistant Secretary's determination that the entity with provisional status is not an HMO is not considered final until—

(1) All administrative, but not judicial, appeal procedures are exhausted; or

(2) The time for requesting administrative review has lapsed without a request for review.

§ 431.593 Prior approval of contracts over $100,000.

FFP is not available in expenditures made under any contract exceeding $100,000 unless prior to the execution of the contract the regional medicaid director has approved in writing the expenditures that can reasonably be expected to be made during the contract period.

§ 431.594 Costs under risk contracts.

Under each contract in which an underwriting risk is assumed by the contractor, the total amount paid by the agency for carrying out the provisions of the contract is a medical assistance cost.

§ 431.595 Costs under no-risk contracts.

Under each contract in which no underwriting risk is assumed by the contractor—

(a) The amount paid by the agency for furnishing medical services to eligible recipients is a medical assistance cost; and

(b) The amount paid by the agency for performing other functions is an administrative cost.

§ 431.596 Costs under fiscal agent contracts.

Under each contract with a fiscal agent—

(a) The amount paid to the provider of medical services is a medical assistance cost; and

(b) The amount paid to the contractor for performing the agreed-upon functions is an administrative cost.

§ 431.597 Nonavailability of FFP.

(a) Except as in paragraph (b), FFP is not available in expenditures for payments to an entity if—

(1) The entity operates on a risk basis; and

(2) The entity provides for—

(i) Inpatient hospital service and any other required Medicaid service; or

(ii) Any three or more of the required Medicaid services.

(b) The limitation under paragraph (a) of this section does not apply to HMOs or health insuring organizations, or to payments made to organizations meeting the criteria of sec. 1903(m)(2)(B) (i), (ii), or (iii) of the Act. These organizations generally include those that received grants under the Public Health Service Act in the fiscal year ending June 30, 1976, certain rural primary health care entities, and certain entities that operated on a prepaid risk basis before 1970.

Subpart M—Relations with Other Agencies

§ 431.610 Relations with standard-setting and survey agencies.

(a) *Basis and purpose.* This section implements—

(1) Sec. 1902(a)(9) of the Act, concerning the designation of State authorities to be responsible for establishing and maintaining health and other standards for institutions participating in medicaid; and

(2) Sec. 1902(a)(33) of the Act, concerning the designation of the State licensing agency to be responsible for determining whether institutions and agencies meet requirements for participation in the State's medicaid program.

(b) *Designated agency responsible for health standards.* A State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to medicaid recipients, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in medicare (see 42 CFR 405.1902). The requirement for establishing and maintaining standards does not apply with respect to Christian Science sanitoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

(c) *Designated agency responsible for standards other than health standards.* The plan must designate the medicaid agency or other appropriate State authority or authorities to be responsible for establishing and maintaining standards, other than those relating to health, for private or public institutions that provide services to medicaid recipients.

(d) *Description and retention of standards.* (1) The plan must describe the standards established under paragraphs (b) and (c) of this section.

(2) The plan must provide that the medicaid agency keeps these standards on file and makes them available to the Administrator upon request.

(e) *Designation of survey agency.* The plan must provide that—

(1) The agency designated in paragraph (b) of this section, or another State agency responsible for licensing health institutions in the State, determines for the medicaid agency if institutions and agencies meet the requirements for participation in the medicaid program; and

(2) The agency staff making the determination under paragraph (e)(1) of this section is the same staff responsible for making similar determinations for institutions or agencies participating under medicare.

(f) *Written agreement required.* The plan must provide for a written agreement (or formal written intra-agency arrangement) between the medicaid agency and the survey agency designated under paragraph (e) of this section, covering the activities of the survey agency in carrying out its responsibilities. The agreement must specify that—

(1) Federal standards and the forms, methods and procedures that the Administrator designates will be used to determine provider eligibility and certification under medicaid;

(2) Inspectors surveying the premises of a provider will—

(i) Complete inspection reports;

(ii) Note on completed reports whether or not each requirement for which an inspection is made is satisfied; and

(iii) Document deficiencies in reports;

(3) The survey agency will keep on file all information and reports used in determining whether participating facilities meet Federal requirements; and

(4) The survey agency will make the information and reports required under paragraph (f)(3) of this section readily accessible to HEW and the medicaid agency as necessary—

(i) For meeting other requirements under the plan; and

(ii) For purposes consistent with the medicaid agency's effective administration of the program.

(g) *Responsibilities of survey agency.* The plan must provide that, in certifying skilled nursing and intermediate care facilities, the survey agency designated under paragraph (e) of this section will—

(1) Review and evaluate the following information as it relates to health and safety requirements:

(i) Medical and independent professional review team reports obtained under Part 456 of this subchapter.

(ii) Statements from facility payroll records that show the average number and types of personnel, in full-time equivalents, on each shift during at least one week, selected by the team to occur irregularly, in each quarter;

(2) Take necessary action to achieve compliance or to withdraw certification; and

(3) Have qualified personnel perform on-site inspections—

(i) At least once during each certification period or more frequently if there is a compliance question; and

(ii) For institutions with deficiencies, within 6 months after initial correction plan approval and every 6 months thereafter as required under §§ 442.112(e) and 442.113(d) of this subchapter.

(h) *FFP for survey responsibilities.* (1) FFP is available in expenditures that the survey agency makes to carry out its survey and certification responsibilities under the agreement specified in paragraph (f) of this section.

(2) FFP is not available in any expenditures that the survey agency makes that are attributable to the State's overall responsibilities under State law and regulations for establishing and maintaining standards.

§ 431.615 Relations with State health and vocational rehabilitation agencies and title V grantees.

(a) *Basis and purpose.* This section implements sec. 1902(a)(11) and (22)(C) of the Act, by setting forth State plan requirements for arrangements and agreements between the medicaid agency and—

(1) State health agencies;

(2) State vocational rehabilitation agencies; and

(3) Grantees under title V of the Act, Maternal and Child Health and Crippled Children's Services.

(b) *Definitions.* For purposes of this section—

"Title V grantee" means the agency, institution, or organization receiving Federal payments for part or all of the cost of any service program or project authorized by title V of the Act, including—

(1) Maternal and child health services;

(2) Crippled children's services;

(3) Maternal and infant care projects;

(4) Children and youth projects; and

(5) Projects for the dental health of children.

(c) *State plan requirements.* A state plan must—

(1) Describe cooperative arrangements with the State agencies that administer, or supervise the administration of, health services and vocational rehabilitation services designed to make maximum use of these services;

(2) Provide for arrangements with title V grantees, under which the medicaid agency will utilize the grantee to furnish services that are included in the State plan;

(3) Provide that all arrangements under this section meet the requirements of paragraph (d); and

(4) Provide, if requested by the title V grantee in accordance with the arrangements made under this section, that the medicaid agency reimburse the grantee or the provider for the cost of services furnished recipients by or through the grantee.

(d) *Content of arrangements.* The arrangements referred to in paragraph (c) must specify, as appropriate—

(1) The mutual objectives and responsibilities or each party to the arrangement;

(2) The services each party offers and in what circumstances;

(3) The cooperative and collaborative relationships at the State level;

(4) The kinds of services to be provided by local agencies; and

(5) Methods for—

(i) Early identification of individuals under 21 in need of medical or remedial services;

(ii) Reciprocal referrals;

(iii) Coordinating plans for health services provided or arranged for recipients;

(iv) Payment or reimbursement;

(v) Exchange of reports of services furnished to recipients;

(vi) Periodic review and joint planning for changes in the agreements;

(vii) Continuous liaison between the parties, including designation of State and local liaison staff; and

(viii) Joint evaluation of policies that affect the cooperative work of the parties.

(e) *Federal financial participation.* FFP is available in expenditures for medicaid services provided to recipients through an arrangement under this section.

§ 431.625 Coordination of medicaid with medicare part B.

(a) *Basis and purpose.* (1) Section 1843(a) of the Act required the Secretary to enter into an agreement with any State that requested that agreement before January 1, 1970, under which the State could enroll certain medicare-eligible recipients under medicare part B by paying their premiums.

(2) Section 1902(a)(10)(C)(ii)(II) of the Act allows the State to meet deductibles, cost sharing, and other charges for recipients enrolled under medicare part B without obligating itself to provide the range of part B benefits to other recipients; and

(3) Section 1903(a)(1) and section 1903(b) of the Act authorize FFP for State payment of medicare part B premiums for certain recipients.

(4) This section—

(i) Specifies the exception, relating to part B coverage, from the requirement to provide comparable services to all recipients; and

(ii) Prescribes FFP rules concerning State payment for medicare premiums and for services that could have been covered under medicare.

(b) *Exception from obligation to provide comparable services; State plan requirement.* (1) The State's payment of premiums, deductibles, cost sharing, or similar charges under part B does not obligate it to provide the full range of part B services to recipients not covered by medicare.

(2) The State plan must specify this exception if it applies.

(c) *Federal financial participation.* (1) No FFP is available in State expenditures for medicare part B premiums for medicaid recipients who receive no money payments under title I, IV-A, X, XIV, XVI (AABD), or XVI (SSI) of the Act. However, FFP is available in these expenditures for—

(i) AFDC families required to be covered under §§ 435.112 and 436.116 of this subchapter, those eligible for continued medicaid coverage despite increased income from employment;

(ii) Recipients required to be covered under §§ 435.114, 435.134, and 436.112 of this subchapter, those eligible for continued medicaid coverage despite increased income from monthly insurance benefits under title II of the Act; and

(iii) Recipients required to be covered under §§ 435.135 of this subchapter, those eligible for continued medicaid coverage despite increased income from cost-of-living increases under title II of the Act.

(2) No FFP is available in State medicaid expenditures that could have been paid for under medicare part B but were not because the person was not enrolled in part B. This limit applies to all recipients eligible for enrollment under part B, whether individually or through an agreement under sec. 1843(a) of the Act. However, FFP is available in expenditures required by 45 CFR 206.10(a)(6)(ii) for retroactive coverage of recipients.

Subpart N—State Programs for Licensing Nursing Home Administrators

§ 431.700 Basis and purpose.

This subpart implements sections 1903(a)(29) and 1908 of the Act which require that the State plan include a State program for licensing nursing home administrators.

§ 431.701 Definitions.

Unless otherwise indicated, the following definitions apply for purposes of this subpart:

"Agency" means the State agency responsible for licensing individual

practitioners under the State's healing arts licensing act.

"Board" means an appointed State board established to carry out a State program for licensing administrators of nursing homes, in a State that does not have a healing arts licensing act or an agency as defined in this section.

"Licensed" means certified by a State agency or board as meeting all of the requirements for a licensed nursing home administrator specified in this subpart.

"Nursing home" means any institution, facility, or distinct part of a hospital that is licensed or formally recognized as meeting nursing home standards established under State law, or that is determined under § 431.704 to be included under the requirements of this subpart. The term does not include—

(a) A Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or

(b) A distinct part of a hospital, if the hospital meets the definition in §§ 440.10 or 440.140 of this subchapter, and the distinct part is not licensed separately or formally approved as a nursing home by the State even though it is designated or certified as a skilled nursing facility.

"Nursing home administrator" means any person who is in charge of the general administration of a nursing home whether or not the person—

(a) Has an ownership interest in the home; or

(b) Shares his functions and duties with one or more other persons.

§ 431.702 State plan requirement.

A State plan must provide that the State has a program for licensing administrators of nursing homes that meets the requirements of §§ 431.703 through 431.713 of this subpart.

§ 431.703 Licensing requirement.

The State licensing program must provide that only nursing homes supervised by an administrator licensed in accordance with the requirements of this subpart may operate in the State.

§ 431.704 Nursing homes designated by other terms.

If a State licensing law does not use the term "nursing home," the HCFA Administrator will determine the term or terms equivalent to "nursing home" for purposes of applying the requirements of this subpart. To obtain this determination, the medicaid agency must submit to the Regional Medicaid Director copies of current State laws that define institutional health care facilities for licensing purposes.

§ 431.705 Licensing authority.

(a) The State licensing program must provide for licensing of nursing home administrators by—

(1) The agency designated under the healing arts act of the State; or

(2) A State licensing board.

(b) The State agency or board must perform the functions and duties specified in §§ 431.707 through 431.713 and the board must meet the membership requirements specified in § 431.706 of this subpart.

§ 431.706 Composition of licensing board.

(a) The board must be composed of persons representing professions and institutions concerned with the care and treatment of chronically ill or infirm elderly patients. However—

(1) A majority of the board members may not be representative of a single profession or category of institution; and

(2) Members not representative of institutions may not have a direct financial interest in any nursing home.

(b) For purposes of this section, nursing home administrators are considered representatives of institutions.

§ 431.707 Standards.

(a) The agency or board must develop, impose, and enforce standards that must be met by individuals in order to be licensed as a nursing home administrator.

(b) The standards must be designed to insure that nursing home administrators are—

(1) Of good character;

(2) Otherwise suitable; and

(3) Qualified to serve because of training or experience in instutitional administration.

§ 431.708 Procedures for applying standards.

The agency or board must develop and apply appropriate procedures and techniques, including examinations and investigations, for determining if a person meets the licensing standards.

§ 431.709 Issuance and revocation of license.

Except as provided in § 431.714 of this subpart, the agency or board must—

(a) Issue licenses to persons who meet the agency's or board's standards; and

(b) Revoke or suspend a license if the agency or board determines that the person holding the license substantially fails to meet the standards.

§ 431.710 Provisional licenses.

To fill a position of nursing home administrator that unexpectedly becomes vacant, the agency or board may issue one provisional license, for a single period not to exceed 6 months. The license may be issued to a person who does not meet all of the licensing requirements established under § 431.707 but who—

(a) Is of good character and otherwise suitable; and

(b) Meets any other standards established for provisional licensure by the agency or board.

§ 431.711 Compliance with standards.

The agency or board must establish and carry out procedures to insure that licensed administrators comply with the standards in this subpart when they serve as nursing home administrators.

§ 431.712 Failure to comply with standards.

The agency or board must investigate and act on all complaints it receives of violations of standards.

§ 431.713 Continuing study and investigation.

The agency or board must conduct a continuing study of nursing homes and administrators within the State to improve—

(a) Licensing standards; and

(b) The procedures and methods for enforcing the standards.

§ 431.714 Waivers.

The agency or board may waive any standards developed under § 431.707 of this subpart for any person who has served in the capacity of a nursing home administrator during all of the 3 calendar years immediately preceding the calendar year in which the State first meets the requirements in this subpart.

§ 431.715 Federal financial participation.

No FFP is available in expenditures by the licensing board for establishing and maintaining standards for the licensing of nursing home administrators.

Subpart O [Reserved]

Subpart P—Quality Control

§ 431.800 Medicaid quality control (MQC) system.

(a) *Basis and purpose.* This section establishes State plan requirements for a medicaid quality control system designed to reduce erroneous expenditures by monitoring eligibility determinations, third-party liability activities, and claims processing.

(Sec. 1902(a)(4) of the Act.)

(b) *Definitions.* For purposes of this section—

"Active case" means an individual or family determined to be currently eligible for medicaid.

"Claims processing error" means FFP has been claimed for a medicaid payment that was made—

(1) For a service not authorized under the State plan;

(2) To a provider not certified for participation in the medicaid program;

(3) For a service already paid for by medicaid; or

(4) In an amount above the allowable reimbursement level for that service.

"Eligibility error" means that medicaid coverage has been certified or payment has been made for a recipient under review who—

(1) Was ineligible when certified or when he received services under the State's plan; or

(2) Had not met recipient liability requirements when certified eligible for medicaid; that is, he had not incurred medical expenses equal to the amount of this excess income over the State's financial eligibility level.

"Negative case action" means a medicaid application that was denied or otherwise disposed of without a determination of eligibility (for instance, because the application was withdrawn or abandoned) or an individual or family for whom medicaid eligibility was terminated.

"State agency" means either the State medicaid agency, or a State agency that is responsible for determining eligibility for medicaid.

"Third-party liability error" means FFP has been claimed for a medicaid payment when—

(1) All or part of the medical services should have been paid for by a third party; and

(2) The State failed to meet the requirements of § 433.135 of this subchapter for considering third party liability.

(c) *State plan requirements.* A State plan must provide for operating a medicaid quality control (MQC) system that meets the requirements of paragraphs (d) through (h) of this section.

(d) *Basic elements of MQC system.* The agency—

(1) Must operate the MQC system in accordance with the policies, sampling methodology, review procedures, and reporting forms and requirements specified in medicaid quality control manuals issued by HCFA;

(2) Must select statistical samples of both active and negative case actions;

(3) Must review each case in the sample to identify eligibility errors; and

(4) Must review any claims pertaining to each active case to identify erroneous payments resulting from—

(i) Ineligibility;

(ii) Recipient understated or overstated liability;

(iii) Third-party liability; and

(iv) Claims processing errors;

(5) In order to verify eligibility information, must conduct field investigations, including—

(i) Personal interviews for each case in the active case sample; and

(ii) Personal interviews for cases in the negative case action sample, to the extent necessary to verify erroneous eligibility determinations; and

(6) Must use 6-month sampling periods, from April through September and from October through March.

(e) *Reporting requirements.* The agency must submit reports to the Administrator, in the form and at the time specified by him, including—

(1) A description of the State's sampling plan for active cases and negative cases;

(2) A monthly report on eligibility case reviews completed during the month for all cases in the active case sample for that month and selected cases from the negative case sample for that month;

(3) A monthly report on payment reviews completed during the month for cases in the active case sample. (States must wait 5 months after each sample month before accumulating claims paid for each case—through the fourth month following the sample month);

(4) A summary report on eligibility findings and payment error findings for all cases in the 6-month sample, to be submitted by May 31 of each year for the previous April–September sampling period, and by November 30 for the October–March sampling period; and

(5) Other data and reports that the Administrator requests.

(f) *Access to records.* The agency, upon request, must provide HEW staff with access to all records pertaining to its MQC reviews to which the State has access.

(g) *Corrective action.* The agency must—

(1) Take action to correct any eligibility, third-party liability, claims processing or negative case action errors found in the sample cases;

(2) Take administrative action to prevent or reduce the incidence of those errors; and

(3) By July 31 each year, submit to the Administrator a report on its error analysis and a corrective action plan.

(h) *Protection of recipient rights.* Any individual performing activities under the medicaid quality control program must do so in a manner consistent with 45 CFR 206.10(a)(10) concerning the rights of the recipient.

PART—432 STATE PERSONNEL ADMINISTRATION

Subpart A—General Provisions

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AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—General Provisions

§ 432.1 Basis and purpose.

This part prescribes regulations to implement sec. 1902(a)(4) of the Act, which relates to a merit system of State personnel administration and training and use of subprofessional staff and volunteers in State medicaid programs, and sec. 1903(a), rates of FFP for medicaid staffing and training costs. It also prescribes regulations, based on the general administrative authority in sec. 1902(a)(4), for State training programs for all staff.

§ 432.2 Definitions.

"Community service aides" means subprofessional staff, employed in a variety of positions, whose duties are an integral part of the agency's responsibility for planning, administration, and for delivery of health services.

"Fringe benefits" means the employer's share of premiums for workmen's compensation, employees' retirement, unemployment compensation, health insurance, and similar expenses.

"Full-time training" means training that requires employees to be relieved of all responsibility for performance of current agency work to participate in a training program.

"Part-time training" means training that allows employees to continue full-time in their agency jobs or requires only partial reduction of work activities to participate in the training activity.

"Skilled professional medical personnel" means physicians, dentists, and other health practitioners; nurses; medical and psychiatric social workers; medical, hospital, and public health administrators, and licensed nursing

home administrators; and other specialized personnel in the field of medical care.

"Staff of other public agencies" means skilled professional medical personnel and supporting staff (as defined in this section), who are employed in State or local agencies other than the medicaid agency, whose duties are directly related to the administration of the medicaid program and are specified in an written agreement with the medicaid agency.

"Subprofessional staff" means persons performing tasks that demand little or no formal education; a high school diploma; or less than 4 years of college.

"Supporting staff" means secretarial, stenographic, clerical, and other subprofessional staff whose activities are directly necessary to the carrying out of the functions which are the responsibility of skilled professional medical personnel, as defined in this section.

"Training program" means a program of educational activities based on the agency's training needs and aimed at insuring that agency staff acquire the knowledge and skills necessary to perform their jobs.

"Volunteer" means a person who contributes personal service to the community through the agency's program but is not a replacement or substitute for paid staff.

§ 432.10 Standards of personnel administration.

(a) *State plan requirement.* A State plan must provide that the requirements of paragraphs (c) through (h) of this section are met.

(b) *Terms.* In this section, "standards" refer to those specified in paragraph (c).

(c) *Methods of personnel administration.* Methods of personnel administration must be established and maintained, in the medicaid agency and in local agencies administering the program, in conformity with:

(1) The standards for a Merit System of Personnel Administration, 45 CFR part 70, and any standards prescribed by the U.S. Civil Service Commission under section 208 of the Intergovernmental Personnel Act of 1970 modifying or superseding these standards; and

(2) 5 CFR part 900, subpart F, Administration of the Standards for Merit System of Personnel Administration.

(d) *Compliance of local jurisdictions.* The medicaid agency must have in effect methods to assure compliance with the standards by local jurisdictions included in the plan.

(e) *Review and adequacy of State laws, regulations, and policies.* The agency must—

(1) Assure that the U.S. Civil Service Commission has determined the adequacy of current State laws, regulations, and policy statements that effect methods of personnel administration in conformity with the standards and (2) submit any changes in them to the Commission for review.

(f) *Statements of acceptance by local agencies.* If the medicaid agency changes from a State-administered to a State-supervised, locally administered program, it must obtain statements of acceptance of the standards from the local agencies.

(g) *Affirmative action plan.* The medicaid agency must have in effect an affirmative action plan for equal employment opportunity, that includes specific action steps and timetables to assure that opportunity, and meets all other requirements of 45 CFR 70.4.

(h) *Submittal of requested materials.* The medicaid agency must submit to HEW, upon request, copies of the affirmative action plan and of the State and local materials that assure compliance with the standards.

Subpart B—Training Programs; Subprofessional and Volunteer Programs

§ 432.30 Training programs: General requirements.

(a) A State plan must provide for a program of training for medicaid agency personnel. (See also §§ 432.31 and 432.32 for training programs for subprofessional staff and for volunteers.)

(b) The program must—

(1) Include initial inservice training for newly appointed staff, and continuing training opportunities to improve the operation of the program;

(2) Be related to job duties performed or to be performed by the persons trained; and

(3) Be consistent with the program objectives of the agency.

§ 432.31 Training and use of subprofessional staff.

(a) *State plan requirement.* A State plan must provide for the training and effective use of subprofessional staff as community service aides, in accordance with the requirements of this section.

(b) *Recruitment and selection.* The medicaid agency must have methods of recruitment and selection that afford opportunity for full-time or part-time employment of persons of low income, including:

(1) Young, middle-aged, and older persons;

(2) Physically and mentally disabled; and

(3) Recipients.

(c) *Merit system.* Subprofessional positions must be subject to merit system requirements except where special exemption is approved on the basis of a State alternative plan for employment of disadvantaged persons.

(d) *Staffing plan.* The agency staffing plan must include the kinds of jobs that subprofessional staff can perform.

(e) *Career service.* The agency must have a career service program that allows persons:

(1) To enter employment at the subprofessional level; and

(2) To progress to positions of increasing responsibility and reward:

(i) In accordance with their abilities; and

(ii) Through work experience and pre-service and in-service training.

(f) *Training, supervision and supportive services.* The agency must have an organized training program, supervision, and supportive services for subprofessional staff.

(g) *Progressive expansion.* The agency must provide for annual increase in the number of subprofessional staff until:

(1) An appropriate ratio of subprofessional and professional staff has been achieved; and

(2) There is maximum use of subprofessional staff as community aides in the operation of the program.

§ 432.32 Training and use of volunteers.

(a) *State plan requirement.* A State plan must provide for the training and use of non-paid or partially paid volunteers in accordance with the requirements of this section.

(b) *Functions of volunteers.* The medicaid agency must make use of volunteers in:

(1) Providing services to applicants and recipients; and

(2) Assisting any advisory committees established by the agency.

As used in this paragraph, "partially paid volunteers" means volunteers who are reimbursed only for actual expenses incurred in giving service, without regard to the value of the service or the time required to provide it.

(c) *Staffing.* The agency must designate a position whose incumbent is responsible for:

(1) The development, organization, and administration of the volunteer program; and

(2) Coordination of the program with related functions.

(d) *Recruitment, selection, training, and supervision.* The agency must have:

(1) Methods of recruitment and selection that assure participation of volunteers of all income levels, in planning capacities and service provision; and

(2) A program of organized training and supervision of volunteers.

(e) *Reimbursement of expenses.* The agency must—

(1) Reimburse volunteers for actual expenses incurred in providing services; and

(2) Assure that no volunteer is deprived of the opportunity to serve because of the expenses involved.

(f) *Progressive expansion.* The agency must provide for annual increase in the number of volunteers used until the volunteer program is adequate for the achievement of the agency's service goals.

Subpart C—Staffing and Training Expenditures

§ 432.50 FFP: Staffing and training costs.

(a) *Availability of FFP.* FFP is available in expenditures for salary or other compensation, fringe benefits, travel, per diem, and training, at rates determined on the basis of the individual's position, as specified in paragraph (b) of this section.

(b) *Rates of FFP.* (1) For skilled professional medical personnel and supporting, staff of the medicaid agency or of other public agencies (as defined in § 432.2), the rate is 75 percent.

(2) For personnel engaged directly in the operation of mechanized claims processing and information retrieval systems, the rate is 75 percent.

(3) For personnel engaged in the design, development, or installation of mechanized claims processing and information retrieval systems, the rate is 50 percent for training and 90 percent for all other costs specified in paragraph (a) of this section.

(4) For personnel of the State licensing agency who are responsible for inspections of skilled nursing or intermediate care facilities, the rate is 100 percent through September 30, 1980:

(i) If a work plan and budget plan relative to this personnel have been approved by the HCFA regional office, and

(ii) Only for those expenditures that are not attributable to the overall cost of meeting the State licensing agency's responsibilities under State law and regulations, but are necessary and proper for carrying out the required inspections.

(5) For personnel administering family planning services and supplies, the rate is 90 percent.

(6) For all other staff of the medicaid agency or other public agencies providing services to the medicaid agency, and for training and other expenses of volunteers, the rate is 50 percent.

(c) *Specific limitations.* (1) Rates of FFP in excess of 50 percent are applicable only to those portions of the individual's working time that are devoted to the kinds of positions or duties that qualify for those rates.

(2) The special matching rates for persons working on mechanized claims processing and information retrieval systems (paragraph (b) (2) and (3) of this section) are applicable only if the design, development and installation, or the operation, have been approved by the Administrator in accordance with part 433, subpart C, of this subchapter.

432.55 Reporting training and administrative costs.

(a) *Scope.* This section identifies activities and costs to be reported as training or administrative costs on quarterly estimate and expenditure reports to HCFA.

(b) *Activities and costs to be reported on training expenditures.* (1) For fulltime training (with no assigned agency duties): Salaries, fringe benefits, dependency allowances, travel, tuition, books, and educational supplies.

(2) For part-time training: Travel, per diem, tuition, books and educational supplies.

(3) For State and local medicaid agency staff development personnel (including supporting staff) assigned fulltime training functions: Salaries, fringe benefits, travel, and per diem. Costs for staff spending less than full time on training for the medicaid program must be allocated between training and administration in accordance with 45 CFR 205.150.

(4) For experts engaged to develop or conduct special programs: Salary, fringe benefits, travel, and per diem.

(5) For agency training activities directly related to the program: Use of space, postage, teaching supplies, and purchase or development of teaching materials and equipment, for example, books and audiovisual aids.

(6) For field instruction in medicaid: Instructors' salaries and fringe benefits, rental of space, travel, clerical assistance, teaching materials and equipment such as books and audiovisual aids.

(c) *Activities and costs not to be reported as training expenditures.* The following activities are to be reported as administrative costs:

(1) Salaries of supervisors (day-to-day supervision of staff is not a training activity); and

(2) Cost of employing students on a temporary basis, for instance, during summer vacation.

§ 432.60 Sources of State share of training expenditures and cost allocation.

(a) *Public funds as the State's share.* (1) Public funds may be considered as the State's share in claiming FFP if they meet the conditions specified in paragraph (a) (2) and (3) of this section.

(2) The public funds are appropriated directly to the State or local medicaid agency, or transferred from other public agencies (including Indian tribes) to the State or local agency and under its administrative control, or certified by the contributing public agency as representing expenditures eligible for FFP under this section.

(3) The public funds are not Federal funds, or are Federal funds authorized by Federal law to be used to match other Federal funds.

(b) *Private donated funds as the State's share.* (1) Funds donated from private sources may be considered as the State's share in claiming FFP only if they meet the conditions specified in paragraph (b) (2) through (4) of this section.

(2) The private funds are transferred to the State or local medicaid agency and are under its administrative control.

(3) The private funds are donated without any restriction which would require their use for the training of particular individuals or at particular facilities or institutions.

(4) The private funds do not revert to the donor's facility or use unless the donor is a non-profit organization, and the medicaid agency, of its own volition, decides to use the donor's facility.

(c) *Cost allocation.* Costs of training are chargeable to medicaid only to the extent that the training benefits that program. If the training benefits both federally funded programs and other programs financed solely with State or local funds, the training costs must be allocated among programs as specified in 45 CFR part 74, appendix C and 45 CFR § 205.150.

PART 433—STATE FISCAL ADMINISTRATION

Sec.

433.1 Purpose.

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433.10 Rates of FFP for program services.
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433.110 Basis and purpose.
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Subpart D—Third Party Liability

433.135 Third party liability: Determination of liability and collection procedures.

AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

§ 433.1 Purpose.

This part specifies the rates of FFP for services and administration, and prescribes requirements, prohibitions, and FFP conditions relating to State fiscal activities.

Subpart A—Federal Matching Provisions

§ 433.10 Rates of FFP for program services.

(a) *Basis.* Sections 1903(a)(1), 1903(g), and 1905(b) provide for payments to States, on the basis of a Federal medical assistance percentage, for part of their expenditures for services under an approved State plan.

(b) *Federal medical assistance percentage (FMAP).*—(1) *Computation.* The FMAP is determined by the formula described in sec. 1905(b) of the Act. Under the formula, if a State's per capita income is equal to the national average per capita income, the Federal share is 55 percent. If a State's per capita income exceeds the national average, the Federal share is lower, with a statutory minimum of 50 percent. If a State's per capita income is lower than the national average, the Federal share is increased, with a statutory maximum of 83 percent. The formula used in determining the State and Federal share is as follows:

State share=(State per capita income)^2/(National per capita income)^2×45 percent
Federal share=100 percent minus the State share (with a minimum of 50 percent and a maximum of 83 percent)

The formula provides for squaring both the State and national average per capita incomes; this procedure magnifies any difference between the State's income and the national average. Consequently, Federal matching to lower income States is increased, and Federal matching to higher income States is decreased, within the statutory 50-83 percent limits. The FMAP for Puerto Rico, the Virgin Islands, and Guam is set by statute at 50 percent and is subject to dollar limitations specified in sec. 1108 of the Act.

(2) *Publication.* The FMAP for each State is published in the FEDERAL REGISTER in each even-numbered year, effective for a 2-year period beginning October 1 of the next year.

(c) *Special provisions.* (1) Under sec. 1903(a)(5) of the Act, the Federal share of State expenditures for family planning services is 90 percent.

(2) Under sec. 1905(b), the Federal share of State expenditures for services provided through Indian Health Service facilities is 100 percent.

(3) Under sec. 1903(g), the FMAP is reduced if the State does not have an effective program to control use of institutional services.

§ 433.15 Rates of FFP for administration.

(a) *Basis.* Section 1903(a) (2)–(5) and (7) of the Act provide for payments to States, on the basis of specified percentages, for part of their expenditures for administration of an approved State plan.

(b) *Activities and rates.* (1) Compensation and training of personnel surveying long-term care facilities: 100 percent, through September 30, 1980. (Sec. 1903(a)(4); 42 CFR 432.50(b)(4).)

(2) Administration of family planning services: 90 percent. (Sec. 1903 (a)(5); 42 CFR 432.50(b)(5).)

(3) Design, development, or installation of mechanized claims processing and information retrieval systems: 90 percent. (Sec. 1903(a)(3)(A)(i); 42 CFR part 433, subpart C, and § 432.50 (b)(3).)

(4) Operation of mechanized claims processing and information retrieval systems: 75 percent. (Sec. 1903(a) (3)(B); 42 CFR part 433, subpart C and § 432.50(b)(2).)

(5) Compensation and training of skilled professional medical personnel and staff directly supporting those personnel: 75 percent. (Sec. 1903(a)(2); 42 CFR 432.50(b)(1).)

(6) All other activities the Secretary finds necessary for proper and efficient administration of the State plan: 50 percent. (Sec. 1903(a)(7).) (See also § 455.300 of this subchapter for FFP at 90 percent for State medicaid fraud control units under sec. 1903(a)(6).)

Subpart B—General Administrative Requirements

§ 433.36 Liens and recoveries.

(a) *Basis and purpose.* This section implements sec. 1902(a)(18) of the Act, which prohibits the State from placing a lien against a recipient's property and restricts the use of adjustments and recoveries against recipients.

(b) *Definition of property.* For purposes of this section, "property" includes the homestead and all other personal and real property in which the recipient has a legal interest.

(c) *State plan requirement.* A State plan must provide that the provisions of paragraphs (d) through (g) of this section are met.

(d) *Prohibition against lien or encumbrance.* No lien or encumbrance may be required from or imposed against any recipient's property prior to his death because of medicaid claims paid or to be paid on his behalf, unless placed as a result of a court judgment because of claims incorrectly paid.

(e) *Recipients under 65 years of age.* If a recipient is under 65 years of age when he receives medicaid—

(1) No lien or encumbrance may be imposed at any time against the recipient's property because of medicaid claims paid or to be paid on his behalf, unless placed as a result of a court judgment because of claims incorrectly paid; and

(2) There may be no adjustment or recovery of medicaid claims correctly paid.

(f) *Recipients 65 years of age or older.* If a recipient was 65 years of age or older when he received medicaid, an adjustment or recovery of medicaid claims correctly paid may be made only after his death, from his estate—

(1) After the death of the surviving spouse, if any; and

(2) When there is no surviving child who is under age 21 or blind or disabled as defined in the plan.

(g) *Prohibition of reduction of money payments.* No money payment under another program may be reduced as a means of recovering medicaid claims incorrectly paid.

§ 433.37 Reporting provider payments to Internal Revenue Service.

(a) *Basis and purpose.* This section, based on section 1902(a)(4) of the Act, prescribes requirements concerning—

(1) Identification of providers; and

(2) Compliance with the information reporting requirements of the Internal Revenue Code.

(b) *Identification of providers.* A State plan must provide for the identification of providers by—

(1) Social security number if—

(i) The provider is in solo practice; or

(ii) The provider is not in solo practice but billing is by the individual practitioner; or

(2) Employer identification number for all other providers.

(c) *Compliance with section 6041 of the Internal Revenue Code.* The plan must provide that the medicaid agency complies with the information reporting requirements of section 6041 of the Internal Revenue Code (26 U.S.C. 6041). Section 6041 requires the filing of annual information returns showing amounts paid to providers, who are identified by name, address, and social security number or employer identification number.

Subpart C—Mechanized Claims Processing and Information Retrieval Systems

§ 433.110 Basis and purpose.

This subpart implements section 1903(a)(3) of the Act, which provides for FFP in State expenditures for the design, development, or installation of mechanized claims processing and information retrieval systems and for the operation of certain systems. Additional HEW regulations and medicaid bureau procedures for implementing these regulations are in 45 CFR Part 74, 45 CFR part 95, subpart F,* and part 7-71-00, Medical Assistance Manual.

§ 433.111 Definitions.

For purposes of this section:

"Advance Planning Document (APD)" means a written plan of action to acquire the proposed system. Content requirements for the APD are in 45 CFR part 95, subpart F,* and in part 7-71-00 of the Medical Assistance Manual.

"Design" or "system design" means the putting together of new or more efficient automatic data processing system. This includes the use of hardware to the extent necessary for the design phase.

"Development" means the definition of system requirements, detailing of system and program specifications, programming, and testing. This includes the use of hardware to the extent necessary for the development phase.

"Hardware" means automatic equipment used for a mechanized claims processing and information retrieval system. This equipment accepts and stores data, performs calculations and other processing steps, and produces information. Hardware includes:

(1) Electronic digital computers;

(2) Peripheral or auxiliary equipment used in support of electronic computers;

(3) Data transmission or communications equipment; and

(4) Data input equipment.

"Improvement" means modification of or addition to an existing operational mechanized claims processing and information retrieval system, which benefits the efficient, economical or effective administration of the State plan.

"Installation" means the integrated testing of programs and subsystems, system conversion, and turnover to operational status. This includes the use of hardware to the extent necessary for the installation phase.

"Mechanized claims processing and information retrieval system" means a system of software and hardware used to process medicaid claims, and to retrieve and produce utilization and management information about services that is required by the medicaid agency or Federal Government for administrative and audit purposes.

"Operation" means the automated processing of claims, payments, and reports. "Operation" includes the use of supplies, software, hardware, and personnel directly associated with the functioning of the mechanized system.

"Software" means computer programs, procedures, and associated documentation used to operate the hardware.

§ 433.112 FFP for design, development, installation or improvement of mechanized claims processing and information retrieval systems.

(a) FFP is available at 90 percent in expenditures for design, development, installation or improvement of a mechanized claims processing and information retrieval system, if the system is approved by the Administrator.

(b) The Administrator will approve the system if the following conditions are met:

(1) The Administrator determines the system is likely to provide more efficient, economical, and effective administration of the State plan.

(2) The system meets the system requirements in part 7-71-00 of the Medical Assistance Manual.

(3) The system is compatible with the claims processing and information retrieval systems used in the administration of medicare for prompt eligibility verification and for processing claims for persons eligible for both programs.

(4) The system supports the data requirements of Professional Standards Review Organizations established under part B of title XI of the Act.

(5) The State owns any software that is designed, developed, installed or improved with 90 percent FFP.

(6) The Department has a royalty-free, non-exclusive, and irrevocable license to reproduce, publish, or otherwise use and authorize others to use software, modifications to software, and documentation that is designed, developed, installed or improved with 90 percent FFP.

(7) The costs of the system are determined in accordance with 45 CFR part 74, appendix C.

(8) The medicaid agency agrees in writing to use the system for the period of time specified in the advance planning document approved by the Administrator or for any shorter period of time that the Administrator determines justifies the Federal funds invested.

(9) The agency agrees in writing that the information in the system will be safeguarded in accordance with 45 CFR 205.50.

§ 433.113 FFP for operation of mechanized claims processing and information retrieval systems.

(a) FFP is available at 75 percent of expenditures for operation of a mechanized claims processing and information retrieval system approved by the Administrator.

(b) The Administrator will approve the system operation if the conditions in § 433.112(b), except (5) and (6), are met and the following conditions are met:

(1) The system has been operating continuously during the period for which FFP is claimed.

(2) The system provides written notice, within 45 days of the payment of a claim, to each person who received services covered by the State plan, or to each person in a sample group of people who received services. This notice must specify—

(i) The service furnished;

(ii) The name of the provider furnishing the service;

(iii) The date on which the service was furnished; and

(iv) The amount of the payment made under the plan for the service.

(3) The written notice must not specify confidential services (as defined by the State) and must not be sent if the only service furnished was confidential.

(4) The system provides both patient and provider profiles for program management and utilization review purposes.

§ 433.114 Termination of FFP for failure to provide access to claims processing and information retrieval systems.

The Administrator will terminate FFP at any time if the medicaid agency fails to provide State and Federal representatives with full access to the system, including on-site inspection. The Administrator may request such access at any time to determine whether the conditions in this subpart are being met.

Subpart D—Third Party Liability

§ 433.135 Third party liability: determination of liability and collection procedures.

(a) *Basis and purpose.* This subpart implements sec. 1902(a)(25) and 1903(d)(2) of the Act by setting forth State plan requirements concerning—

(1) The legal liability of third parties to pay for services provided under the plan; and

(2) Treatment of reimbursements by a third party to a State for medicaid furnished under the plan.

*45 CFR Part 95, Subpart F, is effective 90 days from September 29, 1978, (see 43 FR ; September 29, 1978).

(b) *Definitions.* For purposes of this subpart, "third party" means any entity that is or may be liable to pay all or part of the medical cost of injury, disease, or disability of an applicant or recipient of medicaid.

(c) *Requirements for State plans.* A State plan must provide that requirements of paragraphs (d)-(g) of this section are met.

(d) *Determining liability of third parties.* The medicaid agency must take reasonable measures to determine the legal liability of third parties to pay for services under the plan.

(e) *Payment of claims.* (1) If the agency has determined that—

(i) Third party liability exists for part or all of the services provided to a recipient; and

(ii) The third party will make payment within a reasonable time, the agency must pay only the amount, if any, by which the allowable claim exceeds the amount of the liability.

(2) The agency may not withhold payment for services provided to a recipient if third party liability or the amount of liability cannot be determined, or payments will not be available, within a reasonable time.

(f) *Reimbursement for medicaid.* The agency must seek reimbursement for medicaid to the extent of a third party's legal liability if—

(1) Liability is determined after medicaid is provided to an individual; or

(2) Liability was determined before providing medicaid but the agency failed to make use of it.

(g) *Repayment of Federal share.* If the State has received FFP in medicaid payments for which it receives third party reimbursement, the State must pay the Federal government a portion of the reimbursement determined in accordance with the FMAP for the State.

(h) *Federal financial participation.* FFP is not available in medicaid payments, to the extent of the Federal proportion of the third party liability, if—

(1) Third party liability existed when medicaid payments were made, but was disregarded at that time and not subsequently recovered;

(2) The agency failed to take reasonable steps to collect reimbursement from a third party; or

(3) The agency received reimbursement from a liable third party.

PART 435—ELIGIBILITY IN THE STATES AND DISTRICT OF COLUMBIA

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Subpart A—Introduction, Definitions, and General Provisions

§ 435.1 Introduction.

(a) This section provides a brief explanation of medicaid eligibility as affected by changes in the cash assistance programs under the Social Security Act.

(b) *Medicaid eligibility before enactment of Pub. L. 92-603.*—(1) *Required coverage of the categorically needy.* Before enactment of the Social Security Amendments of 1972 (Pub. L. 92-603, October 30, 1972), which established the Federal program of Supplemental Security Income (SSI), States were required to make all recipients of cash assistance eligible for medicaid. Cash assistance was provided through Federally-assisted, State-administered programs to needy individuals in four categories: Those age 65 or over (title I, Old Age Assistance), the blind (title X, Aid to the Blind), the disabled (title XIV, Aid to the Permanently and Totally Disabled), and certain types of families (title IV-A, Aid to Families with Dependent Children). At State option, cash assistance to the aged, blind, and disabled could be made available under a consolidated program of Aid to the Aged, Blind, and Disabled (title XVI).

Because an eligible individual had to be both categorically related (that is, eligible as aged, blind, disabled, or a member of a family with children deprived of the support of at least one parent) and financially eligible on the basis of income and resources, recipients of cash assistance were termed categorically needy.

(2) *Optional coverage of the categorically needy.* States could elect to cover selected groups of individuals under medicaid who were financially eligible for cash assistance but ineligible because of certain other requirements, or who did not wish to receive cash assistance. Individuals eligible under these optional coverage provisions were considered as categorically needy and were eligible for the same services provided under medicaid to cash assistance recipients.

(3) Coverage of the medically needy. States could limit coverage under medicaid to the categorically needy or could, in addition, extend medicaid to aged, blind, or disabled individuals, or members of families with dependent children, who had too much income to be eligible for cash assistance but not enough for medical care. These individuals were termed "medically needy." A State could set higher levels of income and resources for determining eligibility for medicaid than those used in determining eligibility for cash assistance. Whether it used higher levels for the medically needy or the same level as for the categorically needy, the State had to deduct an applicant's incurred medical expenses from income in determining his eligibility for medicaid. As a result, unlike eligibility for cash assistance, eligibility under the medically needy coverage provision did not depend solely on the absolute amount of an individual's income.

Because a State would be covering more people under the medically needy program, it was permitted to provide more limited medicaid services to the medically needy than to the categorically needy.

(c) *Changes in cash assistance resulting from enactment of Pub. L. 92-603*—(1) *Supplemental Security Income.* Pub. L. 92-603 established a Federal program of cash benefits for the aged, blind, and disabled under a new title XVI of the Act. The SSI program, administered by the Social Security Administration, became effective January 1, 1974, and replaced the previous programs for the aged, blind, and disabled in all jurisdictions of the United States except Puerto Rico, Guam, and the Virgin Islands. In addition to establishing uniform nationwide eligibility standards and requirements, the new title expanded the definition of disability to include individuals under age 18. It also provided for State supplements to the Federal SSI benefit.

(2) *Mandatory State supplements.* In general, most individuals who had been receiving cash assistance under State programs that had used more liberal eligibility requirements than SSI were deemed to meet the new SSI requirements for purposes of medicaid coverage. In addition, States that had

been making higher payments to individuals under the previous programs of cash assistance were required to pay the difference between the SSI benefit and the previous payment. States must provide medicaid to recipients of these mandatory State supplements.

(3) *Optional State supplementation.* States may also pay optional cash supplements either to all aged, blind, and disabled SSI recipients or only to reasonable classifications, such as the aged. Under certain conditions, States may provide medicaid to optional supplement recipients.

(d) *Changes in medicaid eligibility as a result of Pub. L. 92-603.*—(1) *General.* In view of the projected increase in the number of individuals who would qualify for cash assistance under SSI, Pub. L. 92-603 changed the requirements for medicaid coverage in that States are no longer required to cover all aged, blind, and disabled cash (SSI) recipients. It did not change the mandatory coverage of all AFDC recipients.

(2) *SSI option.* States may make SSI recipients eligible for medicaid. In addition, they may provide medicaid to individuals receiving only optional State supplements.

(3) *Restricted eligibility ("section 209(b)") option.* Section 209(b), Pub. L. 92-603 (sec. 1902(f) of the Act), permits States to limit medicaid eligibility for the aged, the blind, or the disabled to individuals who meet eligibility requirements more restrictive than those under SSI. However, States exercising this option must deduct SSI, optional State supplements, and incurred medical expenses from income in determining medicaid eligibility.

Thus, there is no fixed income ceiling under this option; it permits any aged, blind, or disabled individual with enough medical expenses to become eligible.

(4) *Protected medicaid eligibility.* Whichever major option for coverage of the aged, blind, or disabled a State elects, all States are required to provide medicaid to recipients of mandatory State supplements and to certain other groups of individuals who were eligible for medicaid in December 1973 under optional coverage provisions.

§ 435.2 Purpose and applicability.

This part sets forth, for the 50 States and the District of Columbia—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that the medicaid agency must use in determining and redetermining eligibility, and requirements it may not use;

(d) The availability of FFP for providing medicaid and for administering the eligibility provisions of the plan; and

(e) Other requirements concerning eligibility determinations, such as use of an institutionalized individual's income for the cost of care.

(See also 45 CFR 206.10, Application, Determination of Eligibility and Furnishing Assistance, for regulations on eligibility administration. These include such matters as content and processing of applications for medicaid, dates of entitlement, etc.)

§ 435.3 Basis.

This part implements the following sections of the Act, which state eligibility requirements and standards:

1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a) (third paragraph after (37)) Eligibility despite increased monthly insurance benefits under title II.
1902(b) Prohibited conditions for eligibility.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1902(f) State option to restrict medicaid eligibility for aged, blind, or disabled individuals to those who would have been eligible under State plan in effect in January 1972.
1903(f) Income limitations for medically needy and individuals covered by State supplement eligibility requirements.
1904(a)(i)-(vii) List of eligible individuals.
1905(a) (clause following (17)) Prohibitions against providing medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition of essential person.
1905(d)(2) Definition of resident of an intermediate care facility for the mentally retarded.
1905(j) Definition of State supplementary payment.
1905(k) Eligibility of essential spouses of eligible individuals.

§ 435.4 Definitions and use of terms.

As used in this part—

"AABD" means aid to the aged, blind, and disabled under title XVI of the Act;

"AB" means aid to the blind under title X of the Act;

"AFDC" means aid to families with dependent children under title IV-A of the Act;

"APTD" means aid to the permanently and totally disabled under title XIV of the Act;

"Categorically needy" means aged, blind or disabled individuals or families and children who are otherwise eligible for medicaid and who meet the financial eligibility requirements for AFDC, SSI, or an optional State supplement;

"Families and children" refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90, 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but are financially eligible under AFDC rules or medically needy rules (see optional coverage group, § 435.207). It does not include individuals under age 21 whose eligibility for medicaid is based on blindness or disability—for these individuals, SSI rules govern;

"Mandatory State supplement" means a cash payment a State is required to make under section 212, Pub. L. 93-66 (July 9, 1973) to an aged, blind, or disabled individual. Its purpose is to provide an individual with the same amount of cash assistance he was receiving under OAA, AB, APTD, or AABD if his SSI payment is less than that amount;

"Medically needy" means aged, blind, or disabled individuals or families and children who are otherwise eligible for medicaid and whose income and resources are above the limits prescribed for the categorically needy but are within limits set under the medicaid State plan;

"OAA" means old age assistance under title I of the Act;

"OASDI" means old age, survivors, and disability insurance under title II of the Act;

"Optional State supplement" means a cash payment made by a State, under section 1616 of the Act, to an aged, blind, or disabled individual;

"SSI" means supplemental security income under title XVI of the Act.

§ 435.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Subpart B—Mandatory Coverage of the Categorically Needy

§ 435.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

MANDATORY COVERAGE OF FAMILIES AND CHILDREN

§ 435.110 Individuals receiving aid to families with dependent children.

(a) A medicaid agency must provide medicaid to individuals receiving AFDC.

(b) For purposes of this section, an individual is receiving AFDC if his needs are included in determining the amount of the AFDC payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient (see 45 CFR 233.20(a)(2)(vi)) and who could be a recipient under the State's AFDC plan if that plan were as broad as allowed under the Act for FFP.

§ 435.111 Individuals under age 21 who are ineligible for AFDC because of age or school attendance requirements.

The agency must provide medicaid to individuals under age 21 who would be eligible for AFDC if they met the AFDC age or school attendance requirements.

§ 435.112 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment or increased hours of employment, the agency must continue to provide medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4-month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4-month period also begins retroactively with the first month in which AFDC was erroneously paid.

§ 435.113 Individuals who are ineligible for AFDC because of requirements that do not apply under title XIX of the Act.

The agency must provide medicaid to individuals who would be eligible for AFDC except for an eligibility requirement used in that program that is specifically prohibited under title XIX. (See, for example, § 433.36 of this subchapter which prohibits a medicaid agency from placing liens against a recipient's property.)

§ 435.114 Individuals who would be eligible for AFDC except for increased OASDI income under Pub. L. 92-336 (July 1, 1972).

The agency must provide medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving AFDC; or

(2) He would have been eligible for AFDC if he had applied, and the medicaid plan covered this optional group; or

(3) He would have been eligible for AFDC if he were not in a medical institution or intermediate care facility, and the medicaid plan covered this optional group.

(b) The individual would currently be eligible for AFDC except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under AFDC. This includes an individual who—

(1) Meets all current AFDC requirements except for the requirement to file an application; or

(2) Would meet all current AFDC requirements if he were not in a medical institution or intermediate care facility, and the current medicaid plan covers this optional group.

MANDATORY COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.120 Individuals receiving SSI.

Except as allowed under § 435.121, the agency must provide medicaid to aged, blind, and disabled individuals or couples who receive SSI, including—

(a) Individuals receiving SSI pending a final determination of blindness or disability; and

(b) Individuals receiving SSI under an agreement with the Social Security Administration to dispose of resources that exceed the SSI dollar limits on resources.

§ 435.121 Individuals in States using more restrictive requirements for medicaid than the SSI requirements.

(a) The agency may use medicaid eligibility requirements for the aged, blind, or disabled that are more restrictive than the eligibility requirements for SSI or for an optional State supplement program that meets the conditions specified in § 435.230. The agency may be more restrictive in defining blindness or disability, more restrictive in setting financial requirements for income or resources, or both. The requirements may apply to the aged or the blind or the disabled, or to any combination. For example, the agency may use a more restrictive definition of disability for those applying for medicaid as disabled and a more restrictive income requirement for those who apply as aged, but provide medicaid to all individuals receiving SSI on the basis of blindness.

(b) If an agency uses more restrictive requirements under this section—

(1) Each requirement may be no more restrictive than that in effect under the State's medicaid plan on January 1, 1972, and no more liberal than that applied under SSI or an optional State supplement program that meets the conditions of § 435.230; and

(2) In determining financial eligibility of an individual in the category to which the more restrictive requirements apply, the agency must deduct, from the individual's income, his SSI payment, any optional supplement paid under a program described in § 435.230, and incurred medical expenses as specified in § 435.732.

(c) The following sections of this part apply to the agency's use of more restrictive eligibility requirements:

(1) Section 435.135, treatment of individuals who receive OASDI cost-of-living increases.

(2) Section 435.304, medically needy coverage.

(3) Section 435.530, more restrictive definitions of blindness.

(4) Section 435.540, more restrictive definitions of disability.

(5) Sections 435.731 through 435.733, more restrictive income and resource requirements.

(6) Sections 435.812, 435.813, 435.823, 435.831, 435.834, and 435.841, medically needy financial eligibility requirements.

§ 435.122 Individuals who are ineligible for SSI or optional State supplements because of requirements that do not apply under title XIX of the Act.

If an agency provides medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide medicaid to individuals who would be eligible for SSI or optional State supplements except for an eligibility requirement used in those programs that is specifically prohibited under title XIX. (See, for example, § 433.36 of this subchapter which prohibits a medicaid agency from placing liens against a recipient's property.)

§ 435.130 Individuals receiving mandatory State supplements.

The agency must provide medicaid to individuals receiving mandatory State supplements.

§ 435.131 Individuals eligible as essential spouses in December 1973.

(a) The agency must provide medicaid to any person who was eligible for medicaid in December 1973 as an essential spouse of an aged, blind, or disabled individual who was receiving cash assistance, if the conditions in paragraph (b) of this section are met.

An "essential spouse" is defined in section 1905(a) of the Act as one who is living with the individual; whose needs were included in determining the amount of cash payment to the individual under OAA, AB, APTD, or AABD; and who is determined essential to the individual's well-being.

(b) The agency must continue medicaid if—

(1) The aged, blind, or disabled individual continues to meet the December 1973 eligibility requirements of the applicable State cash assistance plan; and

(2) The essential spouse continues to meet the conditions that were in effect in December 1973 under the applicable cash assistance plan for having his needs included in computing the payment to the aged, blind, or disabled individual.

§ 435.132 Institutionalized individuals who were eligible in December 1973.

The agency must provide medicaid to individuals who were eligible for medicaid in December 1973, or any part of that month, as inpatients of medical institutions or residents of intermediate care facilities that were participating in the medicaid program and who—

(a) For each consecutive month after December 1973—

(1) Continue to meet the requirements for medicaid eligibility that were in effect under the State's plan in December 1973 for institutionalized individuals; and

(2) Remain institutionalized; and

(b) Are determined by the State or a professional standards review organization to continue to need institutional care.

§ 435.133 Blind and disabled individuals eligible in December 1973.

The agency must provide medicaid to individuals who—

(a) Meet all current requirements for medicaid eligibility except the criteria for blindness or disability;

(b) Were eligible for medicaid in December 1973 as blind or disabled individuals, whether or not they were receiving cash assistance in December 1973; and

(c) For each consecutive month after December 1973, continue to meet the criteria for blindness or disability and the other conditions of eligibility used under the medicaid plan in December 1973.

§ 435.134 Individuals who would be eligible except for the increase in OASDI benefits under Pub. L. 92-336 (July 1, 1972).

The agency must provide medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving OAA, AB, APTD, or AABD; or

(2) He would have been eligible for one of those programs except that he had not applied, and the medicaid plan covered this optional group; or

(3) He would have been eligible for one of those programs if he were not in a medical institution or intermediate care facility, and the medicaid plan covered this optional group.

(b) The individual would currently be eligible for SSI except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under SSI. This includes an individual who—

(1) Meets all current SSI requirements except for the requirement to file an application; or

(2) Would meet all current SSI requirements if he were not in a medical institution or intermedfate care facility, and the State's medicaid plan covers this optional group.

§ 435.135 Individuals who become ineligible for cash assistance as a result of OASDI cost-of-living increases received after April 1977.

(a) If an agency provides medicaid to aged, blind, or disabled individuals receiving SSI or optional State supplements, it must provide medicaid to individuals who—

(1) Are receiving OASDI;

(2) Were receiving SSI or optional State supplements but become ineligible for those payments because of OASDI cost-of-living increases paid under section 215(i) of the Act after April 1977; and

(3) Would still be eligible for SSI or optional State supplements if the amount of OASDI cost-of-living increases paid after April 1977 were deducted from income.

(b) Cost-of-living increases include the increases received by the individual or his financially responsible spouse.

(c) If the agency adopts more restrictive eligibility requirements than those under SSI, it must provide medicaid to individuals specified in paragraph (a) of this section on the same basis as medicaid is provided to individuals continuing to receive SSI or optional State supplements. If the individual incurs enough medical expenses to reduce his income to the financial eligibility standard for the categorically needy, the agency must cover him as categorically needy. In determining the amount of his income, the agency may deduct the cost-of-living increase paid under section 215(i), up to the amount of the increase that made him ineligible for SSI, and subsequent increases.

Subpart C—Options fo Coverage as Categorically Needy

§ 435.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 435.201 Individuals included in optional groups.

Except where otherwise specified, a medicaid agency that chooses to cover an optional group must provide medicaid to all eligible individuals in that group. For example, in the options applicable to families and children and the aged, blind, or disabled, the agency may not provide medicaid only to families and children; similarly, in the options applicable to the aged, blind, or disabled, it may not cover only the blind.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 435.210 Individuals who would be eligible for but are not receiving cash assistance.

The agency may provide medicaid to individuals who would be eligible for AFDC, SSI, or an optional State supplement as specified in § 435.230 but who are not receiving these benefits.

§ 435.211 Individuals who would be eligible for cash assistance except for their institutional status.

The agency may provide medicaid to individuals in medical institutions and intermediate care facilities who are ineligible for AFDC, SSI, or an optional State supplement because of lower income standards used under these programs to determine eligibility for institutionalized individuals, but who would be eligible for AFDC, SSI, or an optional State supplement as specified in § 435.230 if they were not institutionalized.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 435.220 Individuals who would be eligible for AFDC if child care costs were paid from earnings.

(a) The agency may provide medicaid to individuals who would be eligible for AFDC if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

§ 435.221 Caretaker relatives of children who would be eligible for AFDC if they met age or school attendance requirements.

The agency may provide medicaid to individuals who meet the definition of a caretaker relative under 45 CFR 233.90(c)(1)(v)(A), if they have in their care a child under age 21 who would be eligible for AFDC if he met the AFDC age or school attendance requirements.

§ 435.222 Individuals under age 21 who would be eligible for AFDC but do not qualify as dependent children.

(a) The agency may provide medicaid to individuals under age 21 who would be eligible for AFDC if they met the definition of dependent child. (See 45 CFR 233.90(c)(1).)

(b) The agency may cover all individuals described in paragraph (a) of this section or individuals in reasonable classifications including the following:

(1) Individuals under age 21 in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide medicaid to individuals under age 21 placed in foster homes or private institutions by private nonprofit agencies.

(2) Individuals under age 21 in adoptions subsidized in full or in part by a public agency.

(3) Individuals under age 21 in intermediate care facilites, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

§ 435.223 Individuals who would be eligible for AFDC if coverage under the State's AFDC plan were as broad as allowed under title IV-A.

(a) The agency may provide medicaid to individuals who—

(1) Would be eligible for AFDC if the State's AFDC plan included individuals whose coverage under title IV-A is optional (for example, medicaid may be provided to unborn children or members of families with unemployed fathers even though AFDC is not available to them under the State's AFDC plan); or

(2) Would be eligible for AFDC if the State's AFDC plan did not contain eligibility requirements more restrictive than, or in addition to, those required under title IV-A.

(b) The agency may cover any AFDC optional group without covering all such groups.

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 435.230 Individuals receiving only optional State supplements.

(a) The agency may provide medicaid, in one or more of the following classifications, to individuals who receive only an optional State supplement that meets the conditions specified in paragraph (b) of this section and who would be eligible for SSI except for the level of their income:

(1) All aged individuals.

(2) All blind individuals.

(3) All disabled individuals.

(4) Only aged individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(5) Only blind individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(6) Only disabled individuals in domiciliary facilities or other group living arrangements as defined under SSI.

(7) Individuals receiving a federally administered optional State supplement that meets the conditions specified in this section.

(8) Individuals in additional classifications specified by the Secretary for federally administered supplementary payments under 20 CFR 416.2020(d).

(b) Payments under the optional supplement program must be—

(1) Based on need and paid in cash on a regular basis;

(2) Equal to the difference between the individual's countable income and the income standard used to determine eligibility for supplement. Countable income is income remaining after deductions required under SSI or, at State option, more liberal deductions are made (see § 435.1006 for limitations on FFP in medicaid expenditures for individuals receiving optional State supplements); and

(3) Available to all individuals in the State; however, the plan may provide for variations in the income standard by political subdivision according to cost-of-living differences.

§ 435.231 Individuals in institutions who would not be eligible for cash assistance if they were not institutionalized.

(a) If the agency provides medicaid under § 435.211 to individuals in institutions who would be eligible for AFDC, SSI, or State supplements except for their institutional status, it may also cover aged, blind, and disabled individuals in institutions who—

(1) Because of their income, would not be eligible for SSI or State supplements if they were not institutionalized; but

(2) Have income below a level specified in the plan under § 435.722. (See § 435.1005 for limitations on FFP in medicaid expenditures for individuals specified in this section.)

(b) The agency may cover individuals under this section whether or not the State pays optional supplements.

Subpart D—Optional Coverage of the Medically Needy

§ 435.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 435.301 General rule.

(a) A medicaid agency may provide medicaid to individuals specified in this subpart who—

(1) Either—

(i) Have income that meets the standards in §§ 435.812 through 435.816; or

(ii) If their income is more than allowed under those standards, have incurred medical expenses at least equal to the difference between their income and the applicable income standard; and

(2) Have resources that meet the standards in §§ 435.840 or 435.841.

(b) If the agency chooses this option, the agency must provide medicaid to all the individuals specified in this subpart.

§ 435.310 Medically needy coverage of families and children.

If the agency provides medicaid to the medically needy, it must provide medicaid to the following individuals who meet the income and resource standards in subpart I of this part;

(a) Members of families with dependent children (§ 435.110);

(b) Individuals under age 21 who are ineligible for AFDC because of age or school attendance requirements (§ 435.111);

(c) Individuals who are ineligible for AFDC because of an eligibility requirement under that program that is specifically prohibited under title XIX (§ 435.113);

(d) The following individuals, if the agency provides medicaid to them as categorically needy:

(1) Individuals who would be eligible for AFDC if the State's AFDC plan were as broad as allowed under title IV-A (§ 435.223).

(2) Individuals who would be eligible for AFDC if child care costs were paid from earnings (§ 435.220).

(3) Caretaker relatives of children who are ineligible for AFDC because of age or school attendance requirements (§ 435.221).

(4) Individuals under age 21 who are ineligible for AFDC because they are not dependent children (§ 435.222).

§ 435.320 Medically needy coverage of the aged, blind, and disabled in States that cover individuals receiving SSI.

If the agency provides medicaid to individuals receiving SSI and elects to cover the medically needy, it must provide medicaid to the following individuals who meet the income and resource requirements of subpart I of this part:

(a) Aged, blind, and disabled individuals (§ 435.120).

(b) Aged, blind, and disabled individuals who are ineligible for SSI or an optional State supplement because of an eligibility requirement under those programs that is specifically prohibited under title XIX (§ 435.122).

§ 435.321 Medically needy coverage of the aged, blind, and disabled in States that impose more restrictive eligibility requirements.

(a) If an agency provides medicaid only to those aged, blind, or disabled individuals who meet more restrictive requirements than used under SSI and elects to cover the medically needy, it must provide medicaid to aged, blind, and disabled individuals who—

(1) Have income and resources within the standards established under subpart I of this part; and

(2) If applying as blind or disabled, meet the blindness or disability requirements established under § 435.121.

(b) To determine whether an individual is covered as categorically needy or medically needy, the agency must—

(1) Consider as categorically needy those individuals who meet the State's categorically needy financial standard and (i) who, before their incurred medical expenses are deducted from income, meet the financial eligibility requirements for SSI or a State supplement under § 435.230; or (ii) whose OASDI increases are not counted under §§ 435.134 and 435.135.

(2) Consider as medically needy all other individuals.

§ 435.325 Protected medically needy coverage for blind and disabled individuals eligible in December 1973.

If an agency provides medicaid to the medically needy, it must cover individuals who—

(a) Were eligible as medically needy under the medicaid plan in December 1973 on the basis of the blindness or disability criteria of the AB, APTD, or AABD plan;

(b) For each consecutive month after December 1973, continue to meet—

(1) Those blindness or disability criteria; and

(2) The eligibility requirements for the medically needy under the December 1973 medicaid plan; and

(c) Meet the current requirements for eligibility as medically needy under the medicaid plan except for blindness or disability criteria.

Subpart E—General Eligibility Requirements

§ 435.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

§ 435.401 General rules.

(a) A medicaid agency may not impose any eligibility requirement that is prohibited under title XIX of the Act.

(b) The agency must base any optional group covered under subparts B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and that are consistent with the objectives of title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are—

(1) For families and children, more restrictive than those used under the State's AFDC plan; and

(2) For aged, blind, and disabled individuals, more restrictive than those used under SSI, except for individuals receiving an optional State supplement as specified in § 435.230 or individuals in categories specified by the agency under § 435.121.

§ 435.402 Citizenship and alienage.

The agency must provide medicaid to otherwise eligible residents of the United States who are—

(a) Citizens; or

(b) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law, including any alien who is lawfully present in the United States under sec. 203(a)(7) or sec. 212(d)(5) of the Immigration and Nationality Act.

§ 435.403 State residence.

(a) The agency must provide medicaid to otherwise eligible residents of the State.

(b) For purposes of this section—

(1) "Resident" of a State is an individual who is living in the State voluntarily with the intention of making his home there and is not living in the State for a temporary purpose. A child is a resident of the State in which he is living other than on a temporary basis.

(2) In determining residence, the agency may not consider the reason for which the individual entered the State, except to the extent that the reason may bear upon whether he is residing in the State voluntarily or for a temporary purpose.

(3) An individual retains his residence until he abandons it. Temporary absence from the State, with subsequent returns to the State or intent to return when the purposes of the absence have been accomplished, does not interrupt residence.

§ 435.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

Subpart F—Categorical Requirements for Eligibility

§ 435.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part.

Dependency

§ 435.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures set forth under the State's AFDC plan to determine whether—

(a) An individual under age 21 is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

Age

§ 435.520 Age requirements for the aged and children.

(a) The agency must not impose—

(1) An age requirement of more than 65 years;

(2) An age requirement that excludes an individual under age 21 who would be eligible for AFDC if he met AFDC age or school attendance requirements; or

(3) A lower age requirement than that under the State's AFDC plan.

(b) In determining age, the agency must use the common-law method (under which an age is reached the day before the anniversary of birth), except—

(1) For families and children, the agency must use the popular usage method (under which an age is reached on the anniversary of birth), if this method is used under the State's AFDC plan; and

(2) For aged, blind, or disabled individuals, the agency may use the popular usage method, if the plan provides under § 435.121, for coverage of aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI.

(c) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

BLINDNESS

§ 435.530 Definition of blindness.

(a) *Definition.* The agency must use the same definition of blindness as used under SSI, except that—

(1) In determining the eligibility of individuals whose medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of blindness that was used under the medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the medicaid plan on January 1, 1972.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 435.531 Determinations of blindness.

(a) Except as specified in paragraph (b) of this section, in determining blindness—

(1) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(2) The examiner must submit a report of examination to the medicaid agency; and

(3) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(i) Whether the individual meets the definition of blindness; and

(ii) Whether and when re-examinations are necessary for periodic redeterminations of eligibility, as required under 45 CFR 206.10(a)(9)(iii). Blindness is considered to continue until the reviewing physician determines that the recipient's vision has improved so that he no longer meets the definition.

(b) If an agency provides medicaid to individuals receiving SSI on the basis of blindness, this section does not apply for those individuals.

DISABILITY

§ 435.540 Definition of disability.

(a) *Definition.* The agency must use the same definition of disability as used under SSI, except that—

(1) In determining the eligibility of individuals whose medicaid eligibility is protected under §§ 435.130 through 435.134, the agency must use the definition of disability that was used under the medicaid plan in December 1973; and

(2) The agency may use a more restrictive definition to determine eligibility under § 435.121, if the definition is no more restrictive than that used under the medicaid plan on January 1, 1972.

(b) *State plan requirements.* The State plan must contain the definition of disability.

§ 435.541 Determinations of disability.

(a) Except as specified in paragraph (d) of this section, the agency must obtain a medical report and a social history for individuals applying for medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.

(b) A physician and a social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under 45 CFR § 206.10(a)(9)(iii).

(c) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition. Disability is considered to continue until this determination is made.

(d) If an agency provides medicaid to individuals receiving SSI on the basis of disability, this section does not apply for those individuals.

Subpart G—General Financial Eligibility Requirements

§ 435.600 Scope.

This subpart prescribes general financial requirements for determining the eligibility of both categorically and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I prescribe additional financial requirements.

§ 435.602 Limitation on the financial responsibility of relatives.

Except for a spouse of an individual or a parent for a child who is under age 21 or blind or disabled, the agency must not—

(a) Consider income and resources of any relative available to an individual; nor

(b) Collect reimbursement from any relative for amounts paid by the agency for services provided to an individual.

§ 435.603 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and recipients to take all necessary steps to obtain any annuities, pensions, retirement, and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

Subpart H—Financial Requirements for the Categorically Needy

§ 435.700 Scope.

This subpart prescribes financial requirements for determining the eligibility of categorically needy individuals under subparts B and C of this part. The requirements apply only to individuals who are not receiving AFDC, SSI, or an optional State supplement. The financial eligibility requirements of AFDC, SSI, or the State supplement apply to individuals receiving those payments. This subpart also prescribes requirements for applying an institutionalized recipient's income to cost of care.

FINANCIAL REQUIREMENTS APPLICABLE TO OPTIONAL GROUPS: FAMILIES AND CHILDREN

§ 435.711 General requirements.

In determining eligibility for families and children, a medicaid agency must apply the financial eligibility requirements of the State's AFDC plan.

§ 435.712 Financial responsibility of spouses and parents.

(a) For families and children, the agency must consider income and resources of spouses or parents as available to the individual whether or not they are actually contributed, if they live in the same household. For this purpose, "parent" includes a stepparent if he is equally liable with the natural parent for the support of children under State law of general applicability.

(b) If the spouse or parent does not live with the individual, the agency must consider only income and resources that are actually contributed to the individual from a parent or spouse as available to him.

(c) Even if State law confers adult status below age 21, the agency must consider parental income and resources as available to a child, if he is living with the parent, until he becomes 21.

FINANCIAL ELIGIBILITY REQUIREMENTS APPLICABLE TO OPTIONAL GROUPS: THE AGED, BLIND, AND DISABLED IN STATES COVERING INDIVIDUALS RECEIVING SSI

§ 435.721 General requirements.

(a) This section applies when an agency provides medicaid to—

(1) All SSI recipients or to all SSI recipients and to State supplement recipients; and

(2) One or more of the optional coverage groups specified in §§ 435.210 (eligible for but not receiving cash), 435.211 and 435.231 (institutionalized individuals).

(b) If the agency, under § 435.120, provides medicaid to SSI recipients but not to optional State supplement recipients, it must use the SSI financial eligibility requirements to determine medicaid eligibility of aged, blind, and disabled individuals under the optional provisions of §§ 435.210, 435.211, and 435.231. However, under § 435.231, it may use a higher income standard than SSI to determine eligibility for institutionalized individuals.

(c) If the agency provides medicaid to SSI recipients and, under § 435.230, to individuals who are not receiving SSI but are receiving optional State supplements, the agency must use the following criteria to determine medicaid eligibility under the optional provisions of §§ 435.210, 435.211, and 435.231 for aged, blind, and disabled individuals:

(1) The agency must use the SSI financial eligibility requirements for individuals who would be eligible for SSI but would not be eligible for an optional State supplement.

(2) The agency must use the supplement program's financial eligibility requirements for individuals who would be eligible for an optional State supplement. However, the agency may use a higher income standard than SSI or the State supplement program to determine eligibility of institutionalized individuals under § 435.231.

(d) In determining eligibility under paragraph (b) or (c) of this section, the agency must use the SSI deductions from income and resources and budgeting methods set forth in 20 CFR part 416, unless greater deductions from income and higher income standards are used in an optional State supplement program that meets the requirements of § 435.230.

§ 435.722 Institutionalized individuals who would not be eligible for cash assistance if they were not institutionalized.

(a) If an agency, under § 435.231, provides medicaid to individuals in medical institutions and intermediate care facilities who would not be eligible for SSI or State supplements if they were not institutionalized, the agency must use income standards based on the greater need for financial assistance that the individuals would have if they were not in the institution. The standards may vary by the level of institutional care needed by the individual (hospital, skilled nursing, or intermediate level care), or by other factors related to individual needs. (See § 435.1005 for FFP limits on income standards established under this section.)

(b) In determining the eligibility of individuals under the income standards established under this section, the agency must not take into account income that would be disregarded in determining eligibility for SSI or for an optional State supplement.

(c) The agency must apply the income standards established under this section effective with the first full month of institutionalization.

§ 435.723 Financial responsibility of spouses.

(a) If the agency provides medicaid to SSI recipients, it must meet the requirements of this section in determining eligibility of aged, blind, and disabled individuals under the optional coverage provisions of §§ 435.210, 435.211, and 435.231.

(b) The agency must consider income and resources of spouses living in the same household as available to each other, whether or not they are actually contributed.

(c) If both spouses apply or are eligible as aged, blind, or disabled and cease to live together, the agency must consider their income and resources as available to each other for the first 6 months after the month they cease to live together. After this 6-month period, the agency must consider only the income and resources that are actually contributed by one spouse to the other.

(d) If only one spouse in a couple applies or is eligible and they cease to live together, the agency must consider only the income and resources of the eligible spouse that are actually contributed to the eligible spouse after the month in which they cease to live together.

§ 435.724 Financial responsibility of parents for blind or disabled children.

(a) If the agency provides medicaid to SSI recipients, it must meet the requirements of this section in determining eligibility of blind and disabled children under the optional coverage provisions of §§ 435.210, 435.211, and 235.231.

(b) If the child is under age 18 and is living in the same household with a parent or spouse of a parent, the agency must consider the parent's or spouse's income and resources available to the child, whether or not they are actually contributed. This rule also applies to a child under 21 living in the same household, if he is regularly attending a school, college, or university or is receiving technical training designed to prepare him for gainful employment.

(c) After the month in which the child ceases to live with a parent or spouse of a parent, the agency must consider only the income and resources of that parent or spouse that are actually contributed to the child. This rule applies even if the child returns to the household for periodic visits.

§ 435.725 Post-eligibility treatment of income and resources of institutionalized individuals: Application of patient income to the cost of care.

(a) The agency must reduce its payment to an institution, for services provided to an individual specified in paragraph (b) of this section, by deducting the amounts specified in paragraph (c) from the individual's income.

(b) This section applies to the following individuals in medical institutions and intermediate care facilities:

(1) Individuals receiving cash assistance under SSI or AFDC who are eligible for medicaid under §§ 435.110 or 435.120.

(2) Individuals who would be eligible for AFDC, SSI, or an optional State supplement except for their institutional status and who are eligible for medicaid under §435.211.

(3) Aged, blind, and disabled individuals who are eligible for medicaid, under §435.231, under a higher income standard than the standard used in determining eligibility for SSI or optional State supplements.

(c) In reducing its payment to the institution, the agency must deduct the following amounts, in the following order, from the individual's total income including amounts disregarded in determining eligibility:

(1) A personal needs allowance that is reasonable in amount for clothing and other personal needs of the individual while in the institution. This protected personal needs allowance must be at least—

(i) $25 a month for an aged, blind, or disabled individual, including a child applying for medicaid on the basis of blindness or disability;

(ii) $50 a month for an institutionalized couple if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility; and

(iii) For other individuals, a reasonable amount set by the agency, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled. Although the personal needs allowance is protected for his use, the individual must use it to

pay for any cost-sharing charges the agency imposes under §§ 447.50 through 447.59 of this subchapter, if he has no other income.

(2) For an individual with only a spouse at home, an additional amount for the maintenance needs of the spouse. This amount must be based on a reasonable assessment of need but must not exceed the highest of—

(i) The amount of the income standard used to determine eligibility for SSI for an individual living in his own home, if the agency provides medicaid only to individuals receiving SSI;

(ii) The amount of the highest income standard, in the appropriate category of age, blindness, or disability, used to determine eligibility for an optional State supplement for an individual in his own home, if the agency provides medicaid to optional State supplement recipients under § 435.230; or

(iii) The amount of the medically needy income standard for one person established under § 435.812, if the agency provides medicaid under the medically needy coverage option.

(3) For an individual with a family at home, an additional amount for the maintenance needs of the family. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members living in the home; and

(iii) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard established under subpart I of this part for a family of the same size.

(4) Amounts for incurred expenses for medical or remedial care that are not subject to payment by a third party, including—

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges; and

(ii) Necessary medical or remedial care recognized under State law but not covered under the State's medicaid plan, subject to reasonable limits the agency may establish on amounts of these expenses.

(d) In determining the amount of the individual's income to be used to reduce the agency's payment to the institution, the agency may, for single individuals, deduct an amount (in addition to the personal needs allowance) for maintenance of the individual's home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that the individual is likely to return to his home within that period.

Financial Eligibility for the Aged, Blind, and Disabled in States Using More Restrictive Requirements Than SSI

§ 435.731 General requirements for determining income eligibility in States using more restrictive requirements than SSI.

(a) *Requirements applicable to all individuals.* If the agency, under § 435.121, uses any requirement for aged, blind, or disabled individuals more restrictive than an eligibility requirement under SSI or optional State supplement program, the agency must determine income in accordance with § 435.732 with respect to any category for which more restrictive requirements are imposed. The agency must use the procedures in § 435.732 regardless of the type of restrictive eligibility factor imposed.

(b) *Income standard for institutionalized individuals.* The agency must use lower income standards to determine eligibility for individuals who are in medical institutions or intermediate care facilities than it uses for noninstitutionalized individuals. Those standards must be reasonable in amount for clothing and personal needs of the individual and must be at least—

(1) $25 a month for single individuals; and

(2) $50 a month for an institutionalized coupled if both spouses are aged, blind, or disabled and their income is considered available to each other in determining eligibility.

§ 435.732 Procedures for determining income eligibility.

The agency must determine income eligibility of individuals in the categories specified in § 435.731(a) in the following manner:

(a) *Determining countable income.* Except for individuals in medical institutions and intermediate care facilities, the agency must deduct the following amounts from income to determine the individual's countable income (see § 435.733 for determining countable income for institutionalized individuals):

(1) Any SSI benefit the individual receives.

(2) Any optional State supplement the individual receives.

(3) Increases in OASDI that are deducted under §§ 435.134 and 435.135(c) for individuals specified in those sections.

(4) Other deductions from income applied under the medicaid plan.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section or, for institutionalized individuals, under § 435.733, is equal to or less than the applicable income standard established under §§ 435.121 or 435.731(b), the individual is eligible for medicaid.

(c) *Deduction of incurred medical expenses.* (1) If countable income exceeds the income standard, the agency must deduct from income expenses incurred by the individual or financially responsible relatives for necessary medical and remedial services that are recognized under State law and are not subject to payment by a third party, including medicare and other health insurance premiums, deductibles or coinsurance charges, and copayments or deductibles imposed under §§ 447.51 or 447.53 of this subchapter.

(2) The agency may set reasonable limits on the types of incurred medical expenses to be deducted from income.

(d) *Eligibility based on incurred medical expenses.* If, after incurred medical expenses are deducted, countable income is equal to or less than the income standard, the individual is eligible for medicaid.

§ 435.733 Institutionalized aged, blind, or disabled individuals: Determination of countable income.

For purposes of § 435.732(a), the agency must determine countable income for institutionalized individuals in the following manner:

(a) The agency must consider all of the individual's income available to him without deducting the amounts specified in § 435.732(a) (1)-(4) (SSI and State supplement payments, OASDI increases, and other deductions specified in the medicaid plan);

(b) If the individual has only a spouse at home, the agency must deduct from the individual's income an amount for the spouse's maintenance needs. This amount must be based on a reasonable assessment of need but must not exceed the higher of—

(i) The more restrictive income standard established under § 435.121; or

(ii) The medically needy standard for an individual;

(c) If the individual has a family at home, the agency must deduct from his income an amount for their maintenance needs. This amount must—

(i) Be based on a reasonable assessment of their financial need;

(ii) Be adjusted for the number of family members; and

(iii) Not exceed the higher of the need standard under the State's AFDC plan or the medically needy standard for a family of the same size; and

(d) For an individual with no spouse or family at home, the agency may deduct from his income an amount for maintenance of his home if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that the individual is likely to return to his home within that period.

§ 435.734 Financial responsibility of spouses and parents.

In determining medicaid eligibility of an aged, blind, or disabled individual under requirements more restrictive than those used under SSI, the agency must consider the income and resources of spouses and parents as available to the individual in the manner specified in §§ 435.723 and 435.724 or in a more extensive manner, but not more extensive than the requirements in effect under the medicaid plan on January 1, 1972.

FINANCIAL REQUIREMENTS APPLICABLE TO INDIVIDUALS UNDER PROTECTED COVERAGE PROVISIONS

§ 435.740 Protected medicaid eligibility for individuals eligible in December 1973.

In determining whether individuals continue to meet the income requirements used in December 1973, for purposes of determining eligibility under §§ 435.131, 435.132, and 435.133, the agency must deduct increased OASDI payments to the same extent that these deductions were in effect in December 1973. These deductions are required by section 306 of the Social Security Amendments of 1972 (Pub. L. 92-603) and section 1007 of Pub. L. 91-172 (enacted Dec. 30, 1969), modified by section 304 of Pub. L. 92-603.

Subpart I—Financial Requirements for the Medically Needy

§ 435.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

MEDICALLY NEEDY INCOME STANDARDS

§ 435.811 General requirement.

To determine eligibility of medically needy individuals and families, a medicaid agency must use one income standard for all single individuals and one standard for all families of the same size.

§ 435.812 Medically needy income standard for one person, noninsti- tutionalized.

(a) Except as allowed under paragraph (b) of this section, the agency must use an income standard to determine eligibility of noninstitutionalized individuals that at least equals the highest of the following amounts:

(1) The amount of the payment standard for an individual that is generally used to determine eligibility under the State's AFDC plan.

(2) If the agency provides medicaid to all individuals receiving SSI, the amount of the income standard used to determine eligibility under SSI of an individual in his home.

(3) If the agency provides medicaid, under § 435.230, to individuals receiving only optional State supplements, the amount of the highest income standard generally used to determine eligibility for an optional State supplement of an individual in his home.

(4) If the agency provides medicaid only to aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI, the amount of the highest income standard used to determine medicaid eligibility of an aged, blind, or disabled individual.

(b) An agency may use a lower income standard for individuals if—

(1) The income standard used under paragraph (a) of this section exceeds the maximum dollar amount on income allowed for purposes of FFP under § 435.1007; and

(2) The lower income standard at least equals the maximum amount allowed for purposes of FFP.

§ 435.813 Medically needy income standard for one person, institutionalized.

(a) The agency must use a lower income standard than that specified in § 435.812 to determine eligibility of individuals in medical institutions and intermediate care facilities.

(b) The lower income standard must be reasonable in amount for clothing and personal needs of the individual while in the institution and must be at least—

(1) $25 a month for aged, blind, or disabled individuals including a child applying for medicaid on the basis of blindness or disability; and

(2) A reasonable amount set by the agency for other medically needy individuals, based on a reasonable difference in their personal needs from those of the aged, blind, and disabled.

§ 435.814 Medically needy income standard for two persons, non-institutionalized.

(a) Except as provided in paragraph (b) of this section, the agency must use an income standard to determine eligibility for two persons who are not institutionalized that at least equals the highest of the following amounts:

(1) The amount of the payment standard for a family of two that is generally used to determine eligibility under the State's AFDC plan.

(2) If the agency provides medicaid to all individuals receiving SSI, the amount of the income standard used to determine eligibility under SSI of a couple in which both spouses apply as aged, blind, or disabled and live in the same household.

(3) If the agency provides medicaid, under § 435.230, to individuals receiving only optional State supplements, the amount of the highest income standard generally used to determine eligibility for an optional State supplement for couples in which both spouses apply as aged, blind, or disabled and live in the same household.

(4) If the agency provides medicaid only to aged, blind, or disabled individuals who meet more restrictive eligibility requirements than those under SSI, the amount of the highest income standard used to determine medicaid eligibility of couples in which both spouses apply as aged, blind, or disabled and are living in the same household.

(b) An agency may use a lower income standard for two persons if—

(1) The income standard used under paragraph (a) of this section exceeds the maximum dollar amount on income allowed for purposes of FFP under § 435.1007; and

(2) The lower income standard at least equals the maximum amount allowed for purposes of FFP.

§ 435.815 Medically needy income standards for institutionalized couples.

(a) The agency must use a lower income standard than that specified in § 435.814 to determine the eligibility of couples in a medical institution or intermediate care facility if—

(1) Both spouses apply for medicaid and are aged, blind, or disabled; and

(2) Their income is considered available to each other in determining their eligibility for medicaid.

(b) The lower income standard must be reasonable in amount for clothing and personal needs of the couple while in the institution and must be at least $50 a month.

§ 435.816 Medically needy income standards for three or more persons.

The agency must use an income standard to determine eligibility of families of three or more that at least equals the amount of the payment standard generally used to determine eligibility under the State's AFDC plan for families of the same size. This rule also applies in determining eligibility of an individual under age 21 living with his parents who is not eligible as a dependent child and whose parents' income and resources are considered available to him under § 435.821.

FINANCIAL RESPONSIBILITY OF RELATIVES

§ 435.821 Financial responsibility of relatives: Families and children.

(a) The agency must meet the requirements of this section in determining eligibility, under § 435.310, of medically needy families and children.

(b) The agency must consider income and resources of spouses or parents as available to the individual whether or not they are actually contributed, if they live in the same household. For this purpose, "parent" includes a stepparent if he is equally liable with the natural parent for the support of children under State law of general applicability.

(c) If the spouse or parent does not live with the individual, the agency must consider income and resources that are actually contributed by the spouse or parent as available to him. The agency must use the methods and procedures of the State's AFDC plan to determine whether an individual is living with a spouse or parent.

(d) Even if State law of general applicability confers adult status below age 21, the agency must consider parental income and resources as available to a child, if he is living with the parent, until he becomes 21.

§ 435.822 Financial responsibility of relatives of aged, blind, or disabled individuals in States using SSI eligibility requirements.

(a) The agency must meet the requirements of this section in determining eligibility, under § 435.320 of medically needy aged, blind, or disabled individuals.

(b) For aged, blind, or disabled individuals with spouses—

(1) The agency must consider income and resources of spouses living in the same household as available to each other whether or not they are actually contributed;

(2) If boith spouses apply or are eligible as aged, blind, or disabled and cease to live together, the agency must consider their income and resources as available to each other for the first 6 months after the month they cease to live together. After this 6-month period, the agency must consider only the income and resources that are actually contributed by one spouse to the other; and

(3) If only one spouse in a couple applies or is eligible and they cease to live together, the agency must consider only the income and resources of the ineligible spouse that are actually contributed to the eligible spouse after the month in which they cease to live together.

(c) For blind or disabled children—

(1) If the child is under age 18 and is living in the same household with a parent or spouse of a parent, the agency must consider the parent's or spouse's income and resources as available to the child whether or not they are actually contributed. This rule also applies to a child under 21 living in the same household, if he is regularly attending a school, college, or university or is receiving technical training designed to prepare him for gainful employment;

(2) After the month in which the child ceases to live with a parent or spouse of a parent, the agency must consider only the income and resources of that parent or spouse that are actually contributed to him. This rule applies even if the child returns to the household for periodic visits.

§ 435.823 Financial responsibility of relatives of aged, blind, or disabled individuals in States using more restrictive requirements than SSI.

In determining medicaid eligibility, under § 435.321, of medically needy aged, blind, or disabled individuals, the agency must consider the income and resources of spouses and parents available in the same manner as they are considered available under § 435.734 for categorically needy aged, blind, or disabled individuals.

MEDICALLY NEEDY INCOME ELIGIBILITY

§ 435.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in the following manner:

(a) *Determining countable income.* Except for individuals in medical institutions and intermediate care facilities, the agency must deduct the following amounts from income to determine the individual's countable income. (See § 435.832 for countable income for institutionalized individuals.) The agency must use a prospective period of not more than 6 months to compute income.

(1) For families and children, the agency must deduct amounts that would be deducted in determining eligibility under the State's AFDC plan.

(2) For aged, blind, or disabled individuals in States covering all SSI recipients, the agency must deduct amounts that would be deducted in determining eligibility under SSI. However, the agency must also deduct the highest amounts from income that would be deducted in determining eligibility for optional State supplements if these supplements are paid to all individuals who are receiving SSI or would be eligible for SSI except for their income.

(3) For aged, blind, or disabled individuals in States using income requirements more restrictive than SSI, the agency must deduct amounts that are no more restrictive than those used under the medicaid plan on January 1, 1972 and no more liberal than those deducted in determining eligibility under SSI or an optional State supplement. However, the amounts must be at least the same as those that would be deducted in determining eligibility, under § 435.121, of the categorically needy.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section or, for institutionalized individuals, under § 435.832, is equal to or less than the applicable income standard under §§ 435.812 through 435.816, the individual or family is eligible for medicaid.

(c) *Deduction of incurred medical expenses.* (1) If countable income exceeds the income standard, the agency must deduct from income, in the following order, incurred medical expenses that are not subject to payment by a third party:

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges, incurred by the individual or family or financially responsible relatives, including enrollment fees, copayments, or deductibles imposed under §§ 447.51 or 447.53 of this subchapter.

(ii) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan.

(iii) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan.

(2) The agency may set reasonable limits on the amounts of incurred medical expenses to be deducted from income.

(d) *Eligibility based on incurred medical expenses.* If, after incurred medical expenses are deducted, countable income is equal to or less than the income standard, the individual or family is eligible for the rest of the period for which eligibility is determined.

§ 435.832 Determining countable income: Institutionalized individuals.

To determine countable income for purposes of § 435.831 of medically needy individuals in medical institutions and intermediate care facilities, the agency must deduct the following amounts from the total income available to the individual.

(a) *Deduction for spouse.* If an individual has only a spouse at home, the agency must deduct an amount for the spouse's maintenance needs. This amount must be based on a reasonable assessment of the spouse's financial need but must not exceed the highest of the following amounts:

(1) The amount of the income standard used to determine eligibility under SSI of an individual in his home, if the agency provides medicaid to all individuals receiving SSI.

(2) The amount of the highest income standard generally used to determine eligibility for an optional

State supplement of an individual in his home, if the agency provides medicaid under § 435.230(a) (1) through (3) to aged, blind, or disabled individuals receiving a supplement.

(3) The amount of the highest income standard used to determine medicaid eligibility of aged, blind, or disabled individuals, if the agency provides medicaid under § 435.121 only to aged, blind, or disabled individuals who meet more restrictive income requirements than those under SSI.

(4) The amount of the medically needy income standard for one person established under § 435.812.

(b) *Deduction for family.* If an individual in an institution has a family at home, the agency must deduct an amount for their maintenance needs. This amount must—

(1) Be based on a reasonable assessment of their financial need;

(2) Be adjusted for the number of family members; and

(3) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard for a family of the same size established under § 435.816.

(c) *Deduction for home maintenance.* The agency may, for single individuals, deduct an amount to maintain his home, if—

(1) The amount is deducted for not more than a 6-month period.

(2) A physician has certified that the individual is likely to return to his home within that period.

MEDICALLY NEEDY RESOURCE STANDARDS

§ 435.840 Medically needy resource standards for individuals and two-person families.

(a) Except as allowed in paragraph (b) of this section, the agency must use resource standards to determine eligibility of individuals and two-person families that are at least equal to the higher of the following standards by type of resource, such as a savings account or personal property:

(1) For an individual, the resource standard generally used under the State's AFDC plan or the resource standard used under SSI for an individual.

(2) For a two-person family, the resource standard used under the State's AFDC plan for a two-person family or the resource standard used under SSI for a couple in which both individuals are aged, blind, or disabled.

(b) The agency may use more restrictive resource standards for aged, blind, or disabled individuals or couples if—

(1) The agency uses, under § 435.121, more restrictive resource requirements to determine eligibility of the categorically needy than those used under SSI; and

(2) Those resource requirements are no more restrictive than those used for the categorically needy under § 435.121.

(c) The standard for liquid assets must increase by family size.

§ 435.841 Medically needy resource standards for families of three or more persons.

(a) The agency must use resource standards to determine eligibility of families of three or more that are at least equal to the higher of the following standards by type of resource:

(1) The resource standards generally used under the State's AFDC plan to determine eligibility of families of the same size.

(2) The resource standards used under SSI to determine eligibility of a couple in which both spouses are aged, blind, or disabled.

(b) The standard for liquid assets must increase by family size.

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 435.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives in §§ 435.821, 435.822, or 435.823;

(b) Consider only resources available during the period for which income is computed under § 435.831(a);

(c) For families and children deduct the value of resources that would be deducted in determining eligibility under the State's AFDC plan;

(d) For aged, blind, or disabled individuals in States covering all SSI recipients, deduct the value of resources that would be deducted in determining eligibility under SSI;

(e) For aged, blind, or disabled individuals in States using resource requirements more restrictive than SSI, deduct the value of resources in an amount no more restrictive than those deducted under the medicaid plan on January 1, 1972 and no more liberal than those deducted in determining eligibility under SSI.

However, the amounts must be at least the same as those that would be deducted in determining, under § 435.121, the eligibility of the categorically needy; and

(f) Apply the resource standards established under §§ 435.840 or 435.841.

Subpart J [Reserved]

Subpart K—Federal Financial Participation

§ 435.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP IN EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 435.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in determining and redetermining medicaid eligibility and in providing medicaid to eligible individuals.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

§ 435.1002 FFP for services.

(a) Except for the limitations and conditions specified in §§ 435.1007 and 435.1008, FFP is available in expenditures for medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for medicaid in the month in which the medical care or services were provided except that, for recipients who establish eligibility for medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability. (See 45 CFR 206.10(a)(6) for regulations on retroactive eligibility for medicaid.)

§ 435.1003 Recipients determined ineligible for SSI.

(a) If the Social Security Administration (SSA) notifies an agency that a recipient has been determined ineligible for SSI, FFP is available in medicaid expenditures for services to the recipient as follows:

(1) If the agency receives the SSA notice by the 10th day of the month, FFP is available under this section only through the end of the month unless the recipient requests a hearing under 45 CFR 205.10.

(2) If the agency receives the SSA notice after the 10th day of the month, FFP is available only through the end of the following month, unless the recipient requests a hearing under 45 CFR 205.10.

(3) If a recipient requests a hearing, FFP is available as specified in 45 CFR 205.10.

(b) The agency must take prompt action to determine eligibility after receiving the SSA notice.

§ 435.1004 Recipients overcoming certain conditions of eligibility.

(a) FFP is available, as specified in paragraph (b) of this section, in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a father.

(b) FFP is available for a period not to exceed—

(1) The period during which a recipient of AFDC, SSI or an optional State supplement continues to receive cash payments while these conditions are being overcome; or

(2) For recipients eligible for medicaid only and recipients of AFDC, SSI or an optional State supplement who do not continue to receive cash payments, the second month following the month in which the recipient's medicaid eligibility would have been terminated.

LIMITATIONS ON FFP

§ 435.1005 Recipients in institutions eligible under special outside standard.

For recipients in institutions whose medicaid eligibility is based on a special income standard established under § 435.231, FFP is available in expenditures for services provided to those individuals only if their income before deductions does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual in his own home who has no income or resources.

§ 435.1006 Recipients of optional State supplements only.

FFP is available in expenditures for services provided to individuals receiving optional State supplements but not receiving SSI, if their income before deductions does not exceed 300 percent of the SSI benefit amount payable under section 1611(b)(1) of the Act to an individual who has no income and resources.

§ 435.1007 Medically needy.

(a) FFP is available in expenditures for services provided to medically needy recipients whose annual income after deductions specified in § 436.831 (a) and (c) and § 436.832 does not exceed the following amounts, rounded to the next higher multiple of $100:

(1) For couples and families of two or more, 133⅓ percent of the highest money payment that would ordinarily be made under the State's AFDC plan to a family of the same size without income and resources. If the State's AFDC plan specifies a maximum family size beyond which there is no increase in benefits, the medically needy income levels for families whose size exceeds that maximum will be determined by adding an amount for each family member over the maximum size. These amounts must be reasonably related to the amounts by which the State's AFDC plan increases benefits for additional family members in families below the maximum size.

(2) For individuals, 133⅓ percent of an amount reasonably related to the highest money payment which would ordinarily be made under the State's AFDC plan to a family of two without income and resources.

§ 435.1008 Institutionalized individuals.

(a) Except as provided in paragraph (b) of this section, FFP is not available in expenditures for services provided to—

(i) Individuals who are inmates of public institutions as defined in § 435.1009; or

(ii) Individuals under age 65 who are patients in an institution for tuberculosis or mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) FFP is available in expenditures for services furnished to eligible individuals during the month in which they become inmates of a public institution or patients in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient psychiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

§ 435.1009 Definitions relating to institutional status.

For purposes of FFP, the following definitions apply:

"Active treatment in institutions for the mentally retarded" requires the following:

(a) The individual's regular participation, in accordance with an individual plan of care, in professionally developed and supervised activities, experiences, or therapies.

(b) An individual written plan of care that sets forth measurable goals or objectives stated in terms of desirable behavior and that prescribes an integrated program of activities, experiences or therapies necessary for the individual to reach those goals or objectives. The overall purpose of the plan is to help the individual function at the greatest physical, intellectual, social, or vocational level he can presently or potentially achieve.

(c) An interdisciplinary professional evaluation that—

(1) Is completed, for a recipient, before admission to the institution but not more than 3 months before and, for an individual applying for medicaid after admission, before the institution requests payment;

(2) Consists of complete medical, social, and psychological diagnosis and evaluations and an evaluation of the individual's need for institutional care; and

(3) Is made by a physician, a social worker and other professionals, at least one of whom is a qualified mental retardation professional as defined in § 442.401 of this subchapter.

(d) Reevaluation medically, socially, and psychologically at least annually by the staff involved in carrying out the resident's individual plan of care. This must include review of the individual's progress toward meeting the plan objectives, the appropriateness of the individual plan of care, assessment of his continuing need for institutional care, and consideration of alternate methods of care.

(e) An individual postinsti- tutionalization plan, as part of the individual plan of care, developed before discharge by a qualified mental retardation professional and other appropriate professionals. This must include provision for appropriate services, protective supervision, and other follow-up services in the resident's new environment.

"In an institution" refers to an individual who is admitted to live there and receive treatment or services provided there that are appropriate to his requirements.

"Inmate of a public institution" means a person who is living in a public institution. An individual is not considered an inmate if—

(1) He is in a public educational or vocational training institution for purposes of securing education or vocational training; or

(2) He is in a public institution for a temporary period pending other arrangements appropriate to his needs.

"Inpatient" means a patient who has been admitted to a medical institution on recommendation of a physician or dentist and is receiving room, board, and professional services in the institution on a continuous 24-hour-a-day basis.

"Institution" means an establishment that furnishes (in single or multiple facilities) food, shelter, and some treatment or services to four or more persons unrelated to the proprietor.

"Institution for mental diseases" means an institution that is primarily engaged in providing diagnosis, treatment or care of persons with mental diseases, including medical attention, nursing care and related services. Whether an institution is an institution for mental diseases is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of individuals with mental diseases, whether or not it is licensed as such. An institution for the mentally retarded is not an institution for mental diseases.

"Institution for the mentally retarded or persons with related conditions" means an institution (or distinct part of an institution) that—

(1) Is primarily for the diagnosis, treatment, or rehabilitation of the mentally retarded or persons with related conditions; and

(2) Provides, in a protected residential setting, ongoing evaluation, planning, 24-hour supervision, coordination, and integration of health or rehabilitative services to help each individual function at his greatest ability.

"Institution for tuberculosis" means an institution that is primarily engaged in providing diagnosis, treatment, or care of persons with tuberculosis, including medical attention, nursing care, and related services. Whether an institution is an institution for tuberculosis is determined by its overall character as that of a facility established and maintained primarily for the care and treatment of tuberculosis, whether or not it is licensed as such.

"Medical institution" means an institution that—

(1) Is organized to provide medical care, including nursing and convalescent care;

(2) Has the necessary professional personnel, equipment, and facilities to manage the medical, nursing, and other health needs of patients on a continuing basis in accordance with accepted standards;

(3) Is authorized under State law to provide medical care; and

(4) Is staffed by professional personnel who are responsible to the institution for professional medical and nursing services. The services must include adequate and continual medical care and supervision by a physician; registered nurse or licensed practical nurse supervision and services and nurses' aid services, sufficient to meet nursing care needs; and a physician's guidance on the professional aspects of operating the institution.

"Patient" means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward maintenance, improvement, or protection of health, or lessening of illness, disability, or pain.

"Persons with related conditions" means individuals who have epilepsy, cerebral palsy, or other developmental disabilities as defined under part C of the Developmental Disabilities Services and Facilities Construction Act, Pub. L. 91-517 (enacted Oct. 30, 1970), as amended.

"Public institution" means an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. The term "public institution" does not include a medical institution as defined in this section, an intermediate care facility as defined in §§ 440.140 and 440.150 of this chapter, or a publicly operated community residence that serves no more than 16 residents, as defined in this section.

"Publicly operated community residence that serves no more than 16 residents" is defined in 20 CFR 416.231(b)(6)(i). A summary of that definition is repeated here for the information of readers.

(a) In general, a publicly operated community residence means—

(i) It is publicly operated as defined in 20 CFR 416.231(b)(2).

(ii) It is designed or has been changed to serve no more than 16 residents and it is serving no more than 16; and

(iii) It provides some services beyond food and shelter such as social services, help with personal living activities, or training in socialization and life skills. Occasional medical or remedial care may also be provided as defined in 45 CFR 228.1; and

(2) A publicly operated community residence does not include the following facilities, even though they accommodate 16 or fewer residents:

(i) Residential facilities located on the grounds of, or immediately adjacent to, any large institution or multiple purpose complex.

(ii) Educational or vocational training institutions that primarily provide an approved, accredited, or recognized program to individuals residing there.

(iii) Correctional or holding facilities for individuals who are prisoners, have been arrested or detained pending disposition of charges, or are held under court order as material witnesses or juveniles.

(iv) Hospitals, skilled nursing facilities, and intermediate care facilities.

"Resident of an intermediate care facility" is an individual who is—

(1) In need of and receiving professional services to maintain, improve, or protect health or lessen disability or pain under the direction of a practitioner of the healing arts;

(2) Admitted to an intermediate care facility in accordance with §§ 450.370 through 450.381 of this subchapter;

(3) Under care and supervision 24 hours a day; and

(4) If he is in an institution for the mentally retarded, receiving active treatment as defined in this section.

REQUIREMENTS FOR STATE SUPPLEMENTS

§ 435.1010 Requirement for mandatory State supplements.

(a) Except as specified in paragraph (b) of this section, FFP is not available in medicaid expenditures in any quarter in which the State does not have in effect an agreement with the Secretary under section 212 of Pub. L. 93-66 (July 9, 1973) for minimum mandatory State supplements of the basic SSI benefit.

(b) This section does not apply to any State that meets the conditions of section 212(f) of Pub. L. 93-66.

§ 435.1011 Requirement for maintenance of optinal State supplement expenditures.

(a) This section applies to States that make optional State supplement payments under section 1616(a) of the Act and mandatory supplement payments under section 212(a) of Pub. L. 93-66.

(b) FFP in medicaid expenditures is not available in the following periods, if the State does not have in effect an agreement with the Secretary under section 1618 of the Act to maintain its December 1976 supplementary payment expenditure levels:

(1) Any calendar quarter after June 30, 1977; or

(2) If later, any calendar quarter after the one in which the State first makes supplementary payments.

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PART 436—ELIGIBILITY IN GUAM, PUERTO RICO, AND THE VIRGIN ISLANDS

Subpart A—General Provisions and Definitions

§ 436.1 Purpose and applicability.

This part sets forth, for Guam, Puerto Rico, and the Virgin Islands—

(a) The eligibility provisions that a State plan must contain;

(b) The mandatory and optional groups of individuals to whom medicaid is provided under a State plan;

(c) The eligibility requirements and procedures that a medicaid agency must use in determining and redetermining eligibility, and requirements it may not use; and

(d) The availability of FFP for providing medicaid and for administering the eligibility provisions of the plan.

See also 45 CFR 206.10, Application, Determination of Eligibility and Furnishing Assistance, for regulations on eligibility administration. These include such matters as content and processing of applications for medicaid, dates of entitlement, etc.

§ 436.2 Basis.

This part implements the following sections of the Act, which state requirements and standards for eligibility:

1902(a)(8) Opportunity to apply; assistance must be furnished promptly.
1902(a)(10) Required and optional groups.
1902(a)(12) Determination of blindness.
1902(a)(16) Out-of-State care for State residents.
1902(a)(17) Standards for determining eligibility; flexibility in the application of income eligibility standards.
1902(a)(19) Safeguards for simplicity of administration and best interests of recipients.
1902(a)(34) Three-month retroactive eligibility.
1902(a)(a) (third paragraph after (37)) Eligibility despite increased monthly insurance benefits under title II.
1902(b) Prohibited conditions for eligibility.
1902(e) Four-month continued eligibility for families ineligible because of increased hours or income from employment.
1905(a) (i)-(vii) List of eligible individuals.
1905(a) (clause following (17)) Prohibitions against providing medicaid to certain institutionalized individuals.
1905(a) (second sentence) Definition of essential person.
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§ 436.3 Definitions and use of terms.

As used in this part—

"AABD" means aid to the aged, blind, and disabled under title XVI of the Act;

"AB" means aid to the blind under title X of the Act;

"AFDC" means aid to families with dependent children under title IV-A of the Act;

"APTD" means aid to the permanently and totally disabled under title XIV of the Act;

"Categorically needy" means aged, blind, or disabled individuals or families and children who are otherwise eligible for medicaid and who meet the financial eligibility requirements for OAA, AFDC, AB, APTD, or AABD;

"Families and children" refers to eligible members of families with children who are financially eligible under AFDC or medically needy rules and who are deprived of parental support or care as defined under the AFDC program (see 45 CFR 233.90; 233.100). In addition, this group includes individuals under age 21 who are not deprived of parental support or care but who are financially eligible under AFDC or medically needy rules (see optional coverage group, § 436.222);

"Medically needy" means aged, blind, or disabled individuals or families and children who are otherwise eligible for medicaid and whose income and resources are above the limits prescribed for the categorically needy but are within limits set under the medicaid State plan.

"OAA" means old age assistance under title I of the Act;

"OASDI" means old age, survivors, and disability insurance under title II of the Act.

§ 436.10 State plan requirements.

A State plan must—

(a) Provide that the requirements of this part are met; and

(b) Specify the groups to whom medicaid is provided, as specified in subparts B, C, and D of this part, and the conditions of eligibility for individuals in those groups.

Supart B—Mandatory Coverage of the Categorically Needy

§ 436.100 Scope.

This subpart prescribes requirements for coverage of categorically needy individuals.

§ 436.110 Individuals receiving cash assistance.

(a) A medicaid agency must provide medicaid to individuals receiving cash assistance under OAA, AFDC, AB, APTD, or AABD.

(b) For purposes of this section, an individual is receiving cash assistance if his needs are considered in determining the amount of the payment. This includes an individual whose presence in the home is considered essential to the well-being of a recipient under the State's plan for OAA, AFDC, AB, APTD, or AABD if that plan were as broad as allowed under the Act for FFP.

§ 436.111 Individuals who are not eligible for cash assistance because of a requirement not applicable under medicaid.

The agency must provide medicaid to individuals who would be eligible for OAA, AFDC, AB, APTD, or AABD except for an eligibility requirement used in those programs that is specifically prohibited under title XIX. (See, for example, § 433.36 of this subchapter, which prohibits a medicaid agency from placing liens against a recipient's property.)

§ 436.112 Individuals who would be eligible for cash assistance except for increased OASDI under Pub. L. 92-336 (July 1, 1972).

The agency must provide medicaid to individuals who meet the following conditions:

(a) In August 1972, the individual was entitled to OASDI and—

(1) He was receiving cash assistance; or

(2) He would have been eligible for cash assistance if he had applied, and the medicaid plan covered this optional group; or

(3) He would have been eligible for cash assistance if he were not in a medical institution or intermediate care facility, and the medicaid plan covered this optional group.

(b) The individual would currently be eligible for cash assistance except that the increase in OASDI under Pub. L. 92-336 raised his income over the limit allowed under the cash assistance program. This includes an individual who—

(1) Meets all current requirements for cash assistance except for the requirement to file an application; or

(2) Would meet all current requirements for cash assistance if he were not in a medical institution or intermediate care facility, and the medicaid plan covers this optional group.

§ 436.115 Individuals under 21 who are ineligible for AFDC because of age and school attendance requirements.

The agency must provide medicaid to individuals under age 21 who would be eligible for AFDC if they met the AFDC age or school attendance requirements.

§ 436.116 Families terminated from AFDC because of increased earnings or hours of employment.

(a) If a family loses AFDC solely because of increased income from employment of increased hours of employment, the agency must continue to provide medicaid for 4 months to all members of the family if—

(1) The family received AFDC in any 3 or more months during the 6-month period immediately before the month in which it became ineligible for AFDC; and

(2) At least one member of the family is employed throughout the 4-month period, although this need not be the same member for the whole period.

(b) The 4-month period begins on the date AFDC is terminated. If AFDC benefits are terminated retroactively, the 4-month period also begins retroactively with the first month in which AFDC was erroneously paid.

Subpart C—Options for Coverage as Categorically Needy

§ 436.200 Scope.

This subpart specifies options for coverage of individuals as categorically needy.

§ 436.201 Individuals included in optional group.

Except where otherwise specified, an agency that chooses to cover an optional group must provide medicaid to all eligible individuals in that group. For example, in the options applicable to families and children and the aged, blind, or disabled, the agency may not provide medicaid only to families and children; similarly, in the options applicable to the aged, blind, or disabled, it may not cover only the blind.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN AND THE AGED, BLIND, AND DISABLED

§ 436.210 Individuals who would be eligible for but are not receiving cash assistance.

The agency may provide medicaid to individuals who would be eligible for OAA, AFDC, AB, APTD, or AABD but who are not receiving these benefits.

§ 436.211 Individuals who would be eligible for cash assistance except for their institutional status.

The agency may provide medicaid to individuals in medical institutions and intermediate care facilites who are ineligible for OAA, AFDC, AB, APTD, or AABD because of lower income standards used under those programs to determine eligibility for institutionalized individuals, but who would be eligible for those programs if they were not institutionalized.

§ 436.212 Individuals who would be eligible for cash assistance if the State plan for OAA, AFDC, AB, APTD, or AABD were as broad as allowed under the Act.

(a) The agency may provide medicaid to individuals who—

(1) Would be eligible for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs included individuals whose coverage under title I, IV-A, X, XIV, or XVI is optional (for example, the agency may provide medicaid to unborn children or members of families with unemployed fathers even though the State's AFDC plan does not include them); or

Would qualify for OAA, AFDC, AB, APTD, or AABD if the State's plan under those programs did not contain eligibility requirements more restrictive than, or in addition to, those re-

quired under the appropriate title of the Act. (For example, the agency may provide medicaid to individuals who would meet the Federal definition of disability, 45 CFR 233.80, but who do not meet the State's more restrictive definitions.)

(b) The agency may cover one or more optional groups under any of the titles of the Act without covering all such groups.

OPTIONS FOR COVERAGE OF FAMILIES AND CHILDREN

§ 436.220 Individuals who would be eligible for AFDC if child care costs were paid from earnings.

(a) The agency may provide medicaid to individuals who would be eligible for AFDC if their work-related child care costs were paid from their earnings rather than by a State agency as a service expenditure.

(b) The agency may use this option only if the State's AFDC plan deducts work-related child care costs from income to determine the amount of AFDC.

§ 436.221 Caretaker relatives of children who would be eligible for AFDC if they met age or school attendance requirements.

The agency may provide medicaid to individuals who meet the definition of a caretaker relative under 45 CFR 233.90(c)(1)(v)(A), if they have in their care a child under age 21 who would be eligible for AFDC if they met the AFDC age or school attendance requirements.

§ 436.222 Individuals under age 21 who would be eligible for AFDC but do not qualify as dependent children.

(a) The agency may provide medicaid to individuals under age 21 who would be eligible for AFDC if they met the definition of dependent child. (See 45 CFR 233.90(c)(1).)

(b) The agency may cover all individuals described in paragraph (a) of this section or individuals in reasonable classifications including the following:

(1) Individuals under 21 in foster homes or private institutions for whom a public agency is assuming a full or partial financial responsibility. If the agency covers these individuals, it may also provide medicaid to individuals under age 21 in foster homes or private institutions by private nonprofit agencies.

(2) Individuals under age 21 in adoptions subsidized in full or in part by a public agency.

(3) Individuals under age 21 in intermediate care facilities, if intermediate care facility services are provided under the plan. If the agency covers these individuals, it may also provide medicaid to individuals in intermediate care facilities for the mentally retarded.

(4) Individuals under age 21 receiving active treatment as inpatients in psychiatric facilities or programs, if inpatient psychiatric services for individuals under 21 are provided under the plan.

OPTIONS FOR COVERAGE OF THE AGED, BLIND, AND DISABLED

§ 436.230 Essential spouses of aged, blind, or disabled individuals receiving cash assistance.

The agency may provide medicaid to the spouse of an individual receiving OAA, AB, APTD, or AABD, if—

(a) The spouse is living with the individual receiving cash assistance;

(b) The cash assistance agency has determined that the spouse is essential to the well-being of the individual and has considered the spouse's needs in determining the amount of cash assistance provided to the individual.

Subpart D—Optional Coverage of the Medically Needy

§ 436.300 Scope.

This subpart specifies the option for coverage of medically needy individuals.

§ 436.301 General rules.

(a) A medicaid agency may provide medicaid to individuals specified in this subpart who—

(1) Either—

(i) Have income that meets the standards in §§ 436.812 or 436.813; or

(ii) If their income is more than allowed under those standards, have incurred medical expenses at least equal to the difference between their income and the applicable income standards; and

(2) Have resources that meet the standards in § 436.840.

(b) If the agency chooses this option, the agency must provide medicaid to all individuals specified in this subpart.

§ 436.310 Medically needy coverage of families and children.

If the agency provides medicaid to the medically needy, it must provide medicaid to the following individuals who meet the income and resource standards in subpart I of this part:

(a) Members of families with dependent children (§ 436,110).

(b) Individuals under age 21 who are ineligible for AFDC because of age or school attendance requirements (§ 436.115).

(c) The following individuals, if the agency provides medicaid to them as categorically needy:

(1) Individuals who would be eligible for AFDC if child care costs were paid from earnings (§ 436.220).

(2) Caretaker relatives of children who are ineligible for AFDC because of age or school attendance requirements (§ 436.221).

(3) Individuals under age 21 who are ineligible for AFDC because they are not dependent children (§ 436.222).

§ 436.320 Medically needy coverage of the aged, blind, and disabled.

If the agency provides medicaid to the medically needy, it must provide medicaid to aged, blind, and disabled individuals who would be eligible as categorically needy under § 436.110 except for their income and resources and who meet the income and resource requirements in subpart I of this part.

§ 436.330 Medically needy coverage of families and children and the aged, blind, and disabled.

If the agency provides medicaid to the medically needy, it must provide medicaid to the following individuals who meet the income and resource standards in subpart I of this part:

(a) Individuals who are ineligible for OAA, AFDC, AB, APTD, or AABD because of an eligibility requirement under those programs that is specifically prohibited under title XIX (§ 436.111).

(b) Individuals who would be eligible for OAA, AFDC, AB, APTD, or AABD if those State plans were as broad as allowed under the Act and if the agency provides medicaid to these individuals as categorically needy under § 436.212.

Subpart E—General Eligibility Requirements

§ 436.400 Scope.

This subpart prescribes general requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of the part.

§ 436.401 General rules.

(a) The agency may not impose any eligibility requirement that is prohibited under title XIX.

(b) The agency must base any optional group covered under subpart B and C of this part on reasonable classifications that do not result in arbitrary or inequitable treatment of individuals and groups and are consistent with the objectives of title XIX.

(c) The agency must not use requirements for determining eligibility for optional coverage groups that are more restrictive than those used under the State plans for OAA, AFDC, AB, APTD, or AABD.

§ 436.402 Citizenship and alienage.

The agency must provide medicaid to otherwise eligible residents of the United States who are—

(a) Citizens; or

(b) Aliens lawfully admitted for permanent residence or permanently residing in the United States under color of law, including any alien who is lawfully present in the United States under section 203(a)(7) or section 212(d)(5) of the Immigration and Nationality Act.

§ 436.403 State residence.

(a) The agency must provide medicaid to otherwise eligible residents of the State.

(b) For purposes of this section—

(1) "Resident" of a State is an individual who is living in the State voluntarily with the intention of making his home there and is not living in the State for a temporary purpose. A child is a resident of the State in which he is living other than on a temporary basis.

(2) In determining residence, the agency must not consider the reason for which the individual entered the State, except to the extent that the reason may bear upon whether he is residing in the State voluntarily or for a temporary purpose.

(3) Residence is retained until abandoned. Temporary absence from the State (with subsequent return to the State or intent to return when the purposes of the absence have been accomplished) does not interrupt residence.

§ 436.404 Applicant's choice of category.

The agency must allow an individual who would be eligible under more than one category to have his eligibility determined for the category he selects.

Subpart F—Categorical Requirements for Medicaid Eligibility

§ 436.500 Scope.

This subpart prescribes categorical requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part.

Dependency

§ 436.510 Determination of dependency.

For families with dependent children who are not receiving AFDC, the agency must use the definitions and procedures used under the State's AFDC plan to determine whether—

(a) An individual under age 21 is a dependent child because he is deprived of parental support or care; and

(b) An individual is an eligible member of a family with dependent children.

Age

§ 436.520 Age requirements for the aged and children.

(a) The agency must not impose—

(1) An age requirement of more than 65 years;

(2) An age requirement that excludes an individual under age 21 who would be eligible for AFDC if he met AFDC age or school attendance requirements; or

(3) A lower age requirement than that under the State AFDC plan.

(b) In determining age, the agency must use the common law method (under which an age is reached the day before the anniversary of birth) or the popular usage method (under which a specific age is reached on the anniversary of birth), whichever is used under the corresponding State plan for OAA, AFDC, AB, APTD, or AABD.

(c) The agency may use an arbitrary date, such as July 1, for determining an individual's age if the year, but not the month, of his birth is known.

Blindness

§ 436.530 Definition of blindness.

(a) *Definition.* The agency must use the definition of blindness that is used in the State plan for AB or AABD.

(b) *State plan requirement.* The State plan must contain the definition of blindness, expressed in ophthalmic measurements.

§ 436.531 Determination of blindness.

In determining blindness—

(a) A physician skilled in the diseases of the eye or an optometrist, whichever the individual selects, must examine him, unless both of the applicant's eyes are missing;

(b) The examiner must submit a report of examination to the medicaid agency; and

(c) A physician skilled in the diseases of the eye (for example, an ophthalmologist or an eye, ear, nose, and throat specialist) must review the report and determine on behalf of the agency—

(1) Whether the individual meets the definition of blindness; and

(2) Whether and when reexaminations are necessary for periodic redeterminations of eligibility, as required under 45 CFR 206.10(a)(9)(iii). Blindness is considered to continue until the reviewing physician determines that the recipient's vision no longer meets the definition.

Disability

§ 436.540 Definition of disability.

(a) *Definition.* The agency must use the definition of permanent and total disability that is used in the State plan for APTD or AABD. (See 45 CFR 233.80(a)(1) for the Federal recommended definition of permanent and total disability.)

(b) *State plan requirement.* The State plan must contain the definition of permanent and total disability.

§ 436.541 Determination of disability.

(a) The agency must obtain a medical report and a social history for individuals applying for medicaid on the basis of disability. The medical report must include a diagnosis based on medical evidence. The social history must contain enough information to enable the agency to determine disability.

(b) A physician and social worker, qualified by professional training and experience, must review the medical report and social history and determine on behalf of the agency whether the individual meets the definition of disability. The physician must determine whether and when reexaminations will be necessary for periodic redeterminations of eligibility as required under 45 CFR 206.10(a)(9)(iii).

(c) In subsequently determining disability, the physician and social worker must review reexamination reports and the social history and determine whether the individual continues to meet the definition. Disability is considered to continue until this determination is made.

Subpart G—General Financial Eligibility Requirements

§ 436.600 Scope.

This subpart prescribes general financial requirements for determining the eligibility of both categorically needy and medically needy individuals specified in subparts B, C, and D of this part. Subparts H and I prescribe additional financial requirements.

§ 436.602 Limitation on the financial responsibility of relatives.

Except for a spouse of an individual or a parent for a child who is under 21 or blind or disabled, the agency must not—

(a) Consider income and resources of any relative available to an individual; nor

(b) Collect reimbursement from any relative for amounts paid by the agency for services provided to an individual.

§ 436.603 Applications for other benefits.

(a) As a condition of eligibility, the agency must require applicants and re-

cipients to take all necessary steps to obtain any annuities, pensions, and retirement and disability benefits to which they are entitled, unless they can show good cause for not doing so.

(b) Annuities, pensions, and retirement and disability benefits include, but are not limited to, veterans' compensation and pensions, OASDI benefits, railroad retirement benefits, and unemployment compensation.

Subpart H—Financial Requirements for the Categorically Needy

§ 436.700 Scope.

This subpart prescribes financial requirements for determining the eligibility of categorically needy individuals under subparts B and C of this part. The requirements apply only to individuals who are not receiving cash assistance under OAA, AFDC, AB, APTD, or AABD. The financial eligibility requirements of the cash assistance programs apply to those individuals who are receiving cash assistance.

§ 436.711 Determination of financial eligibility.

In determining eligibility of individuals specified in subparts B and C of this part who are not recipients of cash assistance, the agency must apply the financial eligibility requirements of the State plan for OAA, AFDC, AB, APTD, or AABD that would be used if the individual were applying for cash assistance. This includes requirements on financial responsibility of spouses and parents, except that, in determining eligibility of families and children, the agency must consider parental income and resources as available to a child who is living with the parents until he becomes 21, even if State law confers adult status below age 21.

Subpart I—Financial Requirements for the Medically Needy

§ 436.800 Scope.

This subpart prescribes financial requirements for determining the eligibility of medically needy individuals under subpart D of this part.

Medically Needy Income Standards

§ 436.811 General requirement.

To determine eligibility of medically needy individuals and families, the agency must use one income standard for all single individuals and one standard for all families of the same size.

§ 436.812 Medically needy income standards: Noninstitutionalized individuals.

To determine eligibility of individuals who are not institutionalized, the agency must use—

(a) For an individual or two persons, an income standard that at least equals the amount of the highest income standard used on or after January 1, 1966, to determine eligibility for OAA, AFDC, AB, APTD, or AABD; and

(b) For families of three or more, an income standard that at least equals the amount of the payment standard generally used to determine eligibility under the State's AFDC plan for families of the same size. This rule also applies in determining eligibility of an individual under age 21 living with his parents who is not eligible as a dependent child and whose parents' income and resources are considered available to him under § 436.821.

§ 436.813 Medically needy income standard for individuals in institutions.

(a) The agency must use a lower income standard than that specified in § 436.812 to determine eligibility of individuals in medical institutions and intermediate care facilities.

(b) The lower income standard must be reasonable in amount for clothing and personal needs of the individual.

Financial Responsibility of Relatives

§ 436.821 Financial responsibility of spouses and parents.

In determining eligibility of medically needy individuals, the agency must use the rules for determining whether the income of a spouse or parent is available to the individual that would be used if he were applying for OAA, AFDC, AB, APTD or AABD. However, for families and children, the agency must consider parental income and resources available to a child who is living with the parent until he becomes 21, even if State law confers adult status below age 21.

Medically Needy Income Eligibility and Liability For Payment of Medical Expenses

§ 436.831 Income eligibility.

The agency must determine income eligibility of medically needy individuals in the following manner:

(a) *Determining countable income.* Except for individuals in medical institutions and intermediate care facilities, the agency must, to determine countable income, deduct amounts that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD. (See § 436.832 for countable income for institutionalized individuals.) The agency must use a prospective period of not more than six months to compute income.

(b) *Eligibility based on countable income.* If countable income determined under paragraph (a) of this section or, for institutionalized individuals, under § 436.832, is equal to or less than the applicable income standard under §§ 436.811 or 436.812, the individual is eligible for Medicaid.

(c) *Deduction of incurred medical expenses: Order of deduction.* (1) If countable income exceeds the income standard, the agency must deduct from income, in the following order, incurred medical expenses that are not subject to payment by a third party:

(i) Medicare and other health insurance premiums, deductibles, or coinsurance charges incurred by the individual or family or financially responsible relatives, including enrollment fees, copayments, or deductibles imposed under §§ 447.51 or 447.53 of this subchapter.

(ii) Expenses incurred by the individual or family or financially responsible relatives for necessary medical and remedial services that are recognized under State law but not included in the plan.

(iii) Expenses incurred by the individual or family or by financially responsible relatives for necessary medical and remedial services that are included in the plan.

(2) The agency may set reasonable limits on the amounts of incurred medical expenses to be deducted from income.

(d) *Eligibility based on incurred medical expenses.* If, after incurred medical expenses are deducted, countable income is equal to or less than the income standard, the individual is eligible for the rest of the period for which eligibility is determined.

§ 436.832 Determining countable income: Institutionalized individuals.

To determine countable income for purposes of § 436.831 of medically needy individuals in medical institutions and intermediate care facilities, the agency must deduct the following amounts from the total income available to the individual:

(a) *Deduction for spouse.* If an individual has only a spouse at home, the agency must deduct an amount for the spouse's maintenance needs. This amount must be based on a reasonable assessment of the spouse's financial need but must not exceed the higher of—

(1) The amount of the highest need standard for an individual without income and resources under the State's plan for OAA, AFDC, AB, APTD, or AABD; or

(2) The amount of the medically needy income standard for one person established under § 436.811.

(b) *Deduction for family.* If an individual in an institution has a family at home, the agency must deduct an amount for their maintenance needs. This amount must—

(1) Be based on a reasonable assessment of their financial need;

(2) Be adjusted for the number of family members; and

(3) Not exceed the higher of the need standard for a family of the same size used to determine eligibility under the State's AFDC plan or the medically needy income standard for a family of the same size established under § 436.811.

(c) *Deduction for home maintenance.* The agency may, for a single individual, deduct an amount to maintain his home, if—

(1) The amount is deducted for not more than a 6-month period; and

(2) A physician has certified that the individual is likely to return to his home within that period.

MEDICALLY NEEDY RESOURCE STANDARDS

§ 436.840 Medically needy resource standards.

(a) To determine eligibility of individuals and families under subpart E of this part, the agency must use resource standards that are at least equal to the most liberal standard for resources used to determine eligibility for OAA, AFDC, AB, APTD, or AABD on or after January 1, 1966.

(b) The standards for liquid assets must increase by family size.

DETERMINING ELIGIBILITY ON THE BASIS OF RESOURCES

§ 436.845 Medically needy resource eligibility.

To determine eligibility on the basis of resources for medically needy individuals, the agency must—

(a) Consider only the individual's resources and those that are considered available to him under the financial responsibility requirements for relatives under § 436.821;

(b) Consider only resources available during the period for which income is computed under § 436.831(a);

(c) Deduct the value of resources that would be deducted in determining eligibility under the State's plan for OAA, AFDC, AB, APTD, or AABD; and

(d) Apply the resource standards established under § 436.840.

Subpart J [Reserved]

Subpart K—Federal Financial Participation (FFP)

§ 436.1000 Scope.

This subpart specifies when, and the extent to which, FFP is available in expenditures for determining eligibility and for medicaid services to individuals determined eligible under this part, and prescribes limitations and conditions on FFP for those expenditures.

FFP FOR EXPENDITURES FOR DETERMINING ELIGIBILITY AND PROVIDING SERVICES

§ 436.1001 FFP for administration.

(a) FFP is available in the necessary administrative costs the State incurs in determining and redetermining medicaid eligibility and in providing medicaid to eligible individuals.

(b) Administrative costs include any costs incident to an eye examination or medical examination to determine whether an individual is blind or disabled.

§ 436.1002 FFP for services.

(a) FFP is available in expenditures for medicaid services for all recipients whose coverage is required or allowed under this part.

(b) FFP is available in expenditures for services provided to recipients who were eligible for medicaid in the month in which the medical care or services were provided, except that, for recipients who establish eligibility for medicaid by deducting incurred medical expenses from income, FFP is not available for expenses that are the recipient's liability. (See 45 CFR 206.10 (a)(6) for regulations on retroactive eligibility for medicaid.)

§ 436.1003 Recipients overcoming certain conditions of eligibility.

FFP is available for a temporary period specified in the State plan in expenditures for services provided to recipients who are overcoming certain eligibility conditions, including blindness, disability, continued absence or incapacity of a parent, or unemployment of a father.

§ 436.1004 Institutionalized individuals.

(a) Except as provided in paragraph (b) of this section, FFP is not available in expenditures for services provided to—

(1) Individuals who are inmates of public institutions as defined in § 435.1009; or

(2) Individuals under age 65 who are patients in an institution for tuberculosis or mental diseases unless they are under age 22 and are receiving inpatient psychiatric services under § 440.160 of this subchapter.

(b) FFP is available in expenditures for services provided to eligible individuals during the month in which they become inmates of a public institution or patients in an institution for tuberculosis or mental diseases.

(c) An individual on conditional release or convalescent leave from an institution for mental diseases is not considered to be a patient in that institution. However, such an individual who is under age 22 and has been receiving inpatient pyschiatric services under § 440.160 of this subchapter is considered to be a patient in the institution until he is unconditionally released or, if earlier, the date he reaches age 22.

§ 436.1005 Definitions relating to institutional status.

For purposes of FFP, the definitions in § 435.1009 of this subchapter apply to this part.

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

Sec.

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440.130 Diagnostic, screening, preventive, and rehabilitative services.
440.140 Inpatient hospital services, skilled nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for tuberculosis or mental diseases.
440.150 Intermediate care facility services, other than in institutions for tuberculosis or mental diseases.
440.160 Inpatient pyschiatric services for individuals under age 21.
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Subpart B—Requirements and Limits Applicable to All Services

440.200 Basis, purpose, and scope.
440.210 Required services for the categorically needy.
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440.260 Methods and standards to assure quality of services.
440.270 Religious objections.

AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—Definitions

§ 440.1 Basis and purpose.

This subpart interprets sec. 1905(a) of the act, which lists the services included in the term "medical assistance," and secs. 1905 (c), (d), (f)-(i), and (l), which define some of those services.

§ 440.2 Specific definitions; definitions of services for FFP purposes.

(a) *Specific definitions.* "Outpatient" means a patient who is receiving professional services at an organized medical facility, or distinct part of such a facility, which is not providing him with room and board and professional services on a continuous 24-hour-a-day basis.

"Patient" means an individual who is receiving needed professional services that are directed by a licensed practitioner of the healing arts toward the maintenance, improvement, or protection of health, or lessening of illness, disability, or pain. (See also § 435.1009 of this subchapter for definitions relating to institutional care.)

(b) *Definitions of services for FFP purposes.* Except as limited in part 441, FFP is available in expenditures under the State plan for medical or remedial care and services as defined in this subpart.

§ 440.10 Inpatient hospital services, other than services in an institution for tuberculosis or mental diseases.

"Inpatient hospital services" means services that are ordinarily furnished in a hospital for the care and treatment of an inpatient under the direction of a physician or dentist and that are furnished in an institution that—

(a) Is maintained primarily for the care and treatment of patients with disorders other than tuberculosis or mental diseases;

(b) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting;

(c) Meets the requirements for participation in medicare; and

(d) Has in effect a utilization review plan, applicable to all medicaid patients, that meets the requirements of § 405.1035 of this chapter, unless a waiver has been granted by the Secretary.

§ 440.20 Outpatient hospital services and rural health clinic services.

(a) *"Outpatient hospital services"* means preventive, diagnostic, therapeutic, rehabilitative, or palliative services provided to an outpatient, by or under the direction of a physician or dentist, by an institution that—

(1) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and

(2) Meets the requirements for participation in medicare.

(b) *Rural health clinic services.* If nurse practitioners or physician assistants (as defined in § 481.1 of this chapter) are not prohibited by State law from furnishing primary health care, "rural health clinic services" means the following services when furnished by a rural health clinic that has been certified in accordance with part 481 of this chapter.

(1) Services furnished by a physician within the scope of practice of his profession under State law, if the physician performs the services in the clinic or the services are furnished away from the clinic and the physician has an agreement with the clinic providing that he will be paid by it for such services.

(2) Services furnished by a physician assistant, nurse practitioner, nurse midwife or other specialized nurse practitioner (as defined in §§ 405.2401 and 481.2 of this chapter) if the services are furnished in accordance with the requirements specified in § 405.2414(a) of this chapter.

(3) Services and supplies that are furnished as an incident to professional services furnished by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner. (See §§ 405.2413 and 405.2415 of this chapter for the criteria for determining whether services and supplies are included under this paragraph.)

(4) Part-time or intermittent visiting nurse care and related medical supplies (other than drugs and biologicals) if:

(i) The clinic is located in an area in which the Secretary has determined that there is a shortage of home health agencies (see § 405.2417 of this chapter);

(ii) The services are furnished by a registered nurse or licensed practical nurse or a licensed vocational nurse employed by, or otherwise compensated for the services by, the clinic;

(iii) The services are furnished under a written plan of treatment that is established and reviewed at least every 60 days by a supervising physician of the clinic or that is established by a physician, physician assistant, nurse practitioner, nurse midwife, or specialized nurse practitioner and reviewed and approved at least every 60 days by a supervising physician of the clinic; and

(iv) The services are furnished to a homebound recipient. For purposes of visiting nurse care, a "homebound" recipient means one who is permanently or temporarily confined to his place of residence because of a medical or health condition. He may be considered homebound if he leaves the place of residence infrequently. For this purpose, "place of residence" does not include a hospital or a skilled nursing facility.

(c) *Other ambulatory services furnished by a rural health clinic.* If the State plan covers rural health clinic services, other ambulatory services means ambulatory services other than rural health clinic services, as defined in paragraph (b) of this part, that are otherwise included in the plan and meet specific State plan requirements for furnishing those services. Other ambulatory services furnishd by a rural health clinic are not subject to the physician supervision requirements specified in § 481.8(b) of this chapter, unless required by State law or the State plan.

§ 440.30 Other laboratory and X-ray services.

"Other laboratory and X-ray services" means professional and technical laboratory and radiological services—

(a) Ordered and provided by or under the direction of a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law;

(b) Provided in an office or similar facility other than a hospital outpatient department or clinic; and

(c) Provided by a laboratory that meets the requirements for participation in medicare.

§ 440.40 Skilled nursing facility services for individuals age 21 or older (other than services in an institution for tuberculosis or mental diseases). EPSDT, and family planning services and supplies.

(a) *Skilled nursing facility services.* (1) "Skilled nursing facility services for individuals age 21 or older, other than services in an institution for tuberculosis or mental diseases," means services that are—

(i) Needed on a daily basis and required to be provided on an inpatient basis under §§ 405.127, 405.128, and 405.128a of this chapter;

(ii) Provided by a facility or distinct part of a facility that is certified to meet the requirements for participation under subpart C of part 442 of this subchapter, as evidenced by a valid agreement between the medicaid agency and the facility for providing skilled nursing facility services and making payments for services under the plan; and

(iii) Ordered by and under the direction of a physician.

(2) Skilled nursing facility services includes services provided by any facility located on an Indian reservation and certified by the Secretary as meet-

ing the requirements of subpart K of part 405 of this chapter.

(b) *EPSDT.* "Early and periodic screening and diagnosis and treatment" means—

(1) Screening and diagnostic services to determine physical or mental defects in recipients under age 21; and

(2) Health care, treatment, and other measures to correct or ameliorate any defects and chronic conditions discovered. (See subpart B of part 441 of this subchapter.)

(c) *Family planning services and supplies for individuals of child-bearing age.* [Reserved]

§ 440.50 Physicians' services.

"Physcians' services," whether furnished in the office, the recipient's home, a hospital, a skilled nursing facility, or elsewhere, means services provided—

(a) Within the scope of practice of medicine or osteopathy as defined by State law; and

(b) By or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.

§ 440.60 Medical or other remedial care provided by licensed practitioners.

(a) "Medical care or any other type remedial care provided by licensed practitioners" means any medical or remedial care or services, other than physicians' services, provided by licensed practitioners within the scope of practice as defined under State law.

(b) Chiropractors' services include only services that—

(1) Are provided by a chiropractor who is licensed by the State and meets standards issued by the Secretary under § 405.232b of this chapter; and

(2) Consists of treatment by means of manual manipulation of the spine that the chiropractor is legally authorized by the State to perform.

§ 440.70 Home health services.

(a) "Home health services" means the services in paragraph (b) of this section that are provided to a recipient—

(1) At his place of residence, as specified in paragraph (c) of this section; and

(2) On his physician's orders as part of a written plan of care that the physician reviews every 60 days.

(b) Home health services includes—

(1) Nursing service, as defined in the State Nurse Practice Act, that is provided on a part-time or intermittent basis by a home health agency as defined in paragraph (d) of this section, or if there is no agency in the area, a registered nurse who—

(i) Is currently licensed to practice in the State;

(ii) Receives written orders from the patient's physician;

(iii) Documents the care and services provided; and

(iv) Has had orientation to acceptable clinical and administrative record-keeping from a health department nurse;

(2) Home health aide service provided by a home health agency;

(3) Medical supplies, equipment, and applicances suitable for use in the home; and

(4) Physicial therapy, occupational therapy, or speech pathology and audiology services, provided by a home health agency or by a facility licensed by the State to provide medical rehabilitation services. (See § 441.15 of this subchapter.)

(c) A recipient's place of residence, for home health services, does not include a hospital, skilled nursing facility, or intermediate care facility except for home health services in an intermediate care facility that are not required to be provided by the facility under subparts F and G of part 442 of this subchapter. For example, a registered nurse may provide short-term care for a recipient in an intermediate care facility during an acute illness to avoid the recipient's transfer to a skilled nursing facility.

(d) "Home health agency" means a public or private agency or organization, or part of an agency or organization, that meets requirements for participation in medicare.

(e) A "facility licensed by the State to provide medical rehabilitation services" means a facility that—

(1) Provides therapy services for the primary purpose of assisting in the rehabilitation of disabled individuals through an integrated program of—

(i) Medical evaluation and services; and

(ii) Psychological, social, or vocational evaluation and services; and

(2) Is operated under competent medical supervision either—

(i) In connection with a hospital; or

(ii) As a facility in which all medical and related health services are prescribed by or under the direction of individuals licensed to practice medicine or surgery in the State.

§ 440.80 Private duty nursing services.

"Private duty nursing services" means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of the hospital or skilled nursing facility, and that are provided—

(a) By a registered nurse or a licensed practical nurse;

(b) Under the direction of the recipient's physician; and

(c) To a recipient in his own home or in a hospital or skilled nursing facility.

§ 440.90 Clinic services.

"Clinic services" means preventive, diagnostic, therapeutic, rehabilitative, or palliative items or services provided to an outpatient, by or under the direction of a physician or dentist, by a facility that is not part of a hospital but is organized and operated to provide medical care to outpatients.

§ 440.100 Dental services.

(a) "Dental services" means diagnostic, preventive, or corrective procedures provided by or under the direction of a dentist in the practice of his profession, including treatment of—

(1) The teeth and other structures of the oral cavity; and

(2) Disease, injury, or impairment that may affect the oral or general health of the recipient.

(b) "Dentist" means an individual licensed to practice dentistry or dental surgery.

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

(a) *Physical therapy.* (1) "Physical therapy" means services prescribed by a physician and provided to a recipient by or under the direction of a qualified physical therapist. It includes any necessary supplies and equipment.

(2) A "quilified physical therapist" is an individual who is—

(i) A graduate of a program of physical therapy approved by both the Council on Medical Education of the American Medical Association and the American Physical Therapy Association or its equivalent; and

(ii) Where applicable, licensed by the State.

(b) *Occupational therapy.* (1) "Occupational therapy" means services prescribed by a physician and provided to a recipient by or under the direction of a qualified occupational therapist. It includes any necessary supplies and equipment.

(2) A "qualified occupation therapist" is an individual who is—

(i) Registered by the American Occupational Therapy Association; or

(ii) A graduate of a program in occupational therapy approved by the Council on Medical Education of the American Medical Association and engaged in the supplemental clinical experience required before registration by the American Occupational Therapy Association.

(c) *Services for individuals with speech, hearing, and language disorders.* (1) "Services for individuals with speech, hearing, and language disorders" means diagnostic, screening, preventive, or corrective services provided

by or under the direction of a speech pathologist or audiologist. It includes any necessary supplies and equipment.

(2) A "speech pathologist or audiologist" is an individual who—

(i) Has a certificate of clinical competence from the American Speech and Hearing Association;

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate; or

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

§ 440.120 Prescribed drugs, dentures, prosthetic devices, and eyeglasses.

(a) "Prescribed drugs" means simple or compound substances or mixtures of substances prescribed for the cure, mitigation, or prevention of disease, or for health maintenance that are—

(1) Prescribed by a physician or other licensed practitioner of the healing arts within the scope of this professional practice as defined and limited by Federal and State law;

(2) Dispensed by licensed pharmacists and licensed authorized practitioners in accordance with the State Medical Practice Act; and

(3) Dispensed by the licensed pharmacist or practitioner on a written prescription that is recorded and maintained in the pharmacist's or practitioner's records.

(b) "Dentures" are artificial structures made by or under the direction of a dentist to replace a full or partial set of teeth.

(c) "Prosthetic devices" means replacement, corrective, or supportive devices prescribed by a physician or other licensed practitioner of the healing arts within the scope of his practice as defined by State law to—

(1) Artificially replace a missing portion of the body;

(2) Prevent or correct physical deformity or malfunction; or

(3) Support a weak or deformed portion of the body.

(d) "Eyeglasses" means lenses, including frames, and other aids to vision prescribed by a physician skilled in diseases of the eye or an optometrist.

§ 440.130 Diagnostic, screening, preventive, and rehabilitative services.

(a) "Diagnostic services," except as otherwise provided under this subpart, includes any medical procedures or supplies recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, to enable him to identify the existence, nature, or extent of illness, injury, or other health deviation in a recipient.

(b) "Screening services" means the use of standardized tests given under medical direction in the mass examination of a designated population to detect the existence of one or more particular diseases or health deviations or to identify for more definitive studies individuals suspected of having certain diseases.

(c) "Preventive services" means services provided by a physician or other licensed practitioner of the healing arts within the scope of his practice under State law to—

(1) Prevent disease, disability, and other health conditions or their progression;

(2) Prolong life; and

(3) Promote physical and mental health and efficiency.

(d) "Rehabilitative services," except as otherwise provided under this subpart, includes any medical or remedial services recommended by a physician or other licensed practitioner of the healing arts, within the scope of his practice under State law, for maximum reduction of physical or mental disability and restoration of a recipient to his best possible functional level.

§ 440.140 Inpatient hospital services, skilled nursing facility services, and intermediate care facility services for individuals age 65 or older in institutions for tuberculosis or mental diseases.

(a) *Inpatient hospital services.* (1) "Inpatient hospital services for individuals age 65 or older in institutions for tuberculosis or mental diseases" means services provided under the direction of a physician for the care and treatment of recipients in—

(i) An institution for tuberculosis that meets the requirements under medicare, § 405.1036 of this chapter; and

(ii) An institution for mental diseases that meets the requirements under medicare, §§ 405.1035 and 405.1036 of this chapter, except the requirements for admission reviews under § 405.1035(f) of this chapter, or utilization review under § 405.1035 of this chapter if the institution has been granted a waiver under sec. 1903(i)(4) and subpart H of part 456 of this subchapter.

(2) "Institution for mental diseases" means an institution that is primarily engaged in providing diagnosis, treatment, or care of individuals with mental diseases, including medical care, nursing care, and related services.

(3) "Institution for tuberculosis" means an institution that is primarily engaged in providing diagnosis, treatment, or care of individuals with tuberculosis, including medical attention, nursing care, and related services.

(b) *Skilled nursing facility services.* "Skilled nursing facility services for individuals age 65 or older in institutions for tuberculosis or mental diseases" means skilled nursing facility services as defined in § 440.40 that are provided in institutions for tuberculosis or mental diseases, as defined in paragraph (a) of this section.

(c) *Intermediate care facility services.* "Intermediate care facility services for individuals age 65 or older in institutions for tuberculosis or mental diseases" means intermediate care facility services as defined in § 440.150 of this subpart, that are provided to recipients who are—

(1) Determined under §§ 456.360–456.372 of this subchapter to be in need of services; and

(2) In institutions for tuberculosis and mental diseases, as defined in paragraph (a) of this section.

§ 440.150 Intermediate care facility services, other than in institutions for tuberculosis or mental diseases.

(a) "Intermediate care facility services, other than in an institution for tuberculosis or mental diseases" means services provided in a facility that—

(1) Fully meets the requirements for a State license to provide, on a regular basis, health-related services to individuals who do not require hospital or skilled nursing facility care, but whose mental or physical condition requires services that—

(i) Are above the level of room and board; and

(ii) Can be made available only through institutional facilities;

(2) Has been certified to meet the requirements of subpart C of part 442 of this subchapter as evidenced by a valid agreement between the medicaid agency and the facility for providing intermediate care facility services and making payments for services under the plan; and

(3) Meets the conditions of subpart E of part 442 of this subchapter.

(b) "Intermediate care facility services" include services—

(1) Considered appropriate by the State and provided by a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass.; or

(2) Provided by a facility located on an Indian reservation that—

(i) Furnishes, on a regular basis, health-related services; and

(ii) Is certified by the Secretary to meet the standards in subpart E of part 442 of this subchapter.

(c) "Intermediate care facility services" may include services in an institution for the mentally retarded or persons with related conditions if—

(1) The primary purpose of the institution is to provide health or rehabili-

tative services for mentally retarded individuals or persons with related conditions;

(2) The institution meets the standards in subpart E of part 442 of this subchapter; and

(3) The mentally retarded recipient for whom payment is requested is receiving active treatment as defined in § 435.1009.

(d) "Intermediate care facility services" may include services provided in a distinct part of a facility other than an intermediate care facility if the distinct part—

(1) Meets all requirements for an intermediate care facility;

(2) Is an identifiable unit, such as an entire ward or contiguous ward, a wing, floor, or building;

(3) Consists of all beds and related facilities in the unit;

(4) Houses all recipients for whom payment is being made for intermediate care facility services, except as provided in paragraph (e) of this section;

(5) Is clearly identified; and

(6) Is approved in writing by the survey agency.

(e) If a State includes as intermediate care facility services those services provided by a distinct part of a facility other than an intermediate care facility, it may not require transfer of a recipient within or between facilities if, in the opinion of the attending physician, it might be harmful to the physical or mental health of the recipient.

§ 440.160 Inpatient phychiatric services for individuals under age 21.

"Inpatient psychiatric services for individuals under age 21" means services that—

(a) Are provided under the direction of a physician;

(b) Are provided in a facility or program accredited by the Joint Commission on Accreditation of Hospitals; and

(c) Meet the requirements in subpart D of part 441.

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) *Transportation.* (1) "Transportation" includes expenses for transportation and other related travel expenses determined to be necessary by the agency to secure medical examinations and treatment for a recipient.

(2) Transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency. If other arrangements are made to assure transportation under § 431.52 of this subchapter, FFP is available as an administrative cost.

(3) "Travel expenses" include—

(i) The cost of transportation for the recipient by ambulance, taxicab, common carrier, or other appropriate means;

(ii) The cost of meals and lodging en route to and from medical care, and while receiving medical care; and

(iii) The cost of an attendant to accompany the recipient, if necessary, and the cost of the attendant's transportation, meals, lodging, and, if the attendant is not a member of the recipient's family, salary.

(b) *Services of Christian Science nurses.* "Services of Christian Science nurses" mean services provided by nurses who are listed and certified by the First Chruch of Christ, Scientist, Boston, Mass., if—

(1) The services have been requested by the recipient; and

(2) The services are provided—

(i) By or under the supervision of a Christian Science visiting nurse organization listed and certified by the First Church of Christ, Scientist, Boston, Mass.; or

(ii) As private duty services to a recipient in his home or in a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Mass., if the recipient requires individual and continuous care beyond that available from a visiting nurse or that routinely provided by the nursing staff of the sanatorium.

(c) *Services in Christian Science sanatoriums.* "Services in Christian Science sanatoriums" means services provided in Christian Science sanatoriums that are operated by, or listed and certified by, the First Church of Christ, Scientist, Boston, Mass.

(d) *Skilled nursing facility services for individuals under age 21.* "Skilled nursing facility services for individuals under 21" means those services specified in § 440.40 that are provided to recipients under 21 years of age.

(e) *Emergency hospital services.* "Emergency hospital services" means services that—

(1) Are necessary to prevent the death or serious impairment of the health of a recipient; and

(2) Because of the threat to the life or health of the recipient necessitate the use of the most accessible hospital available that is equipped to furnish the services, even if the hospital does not currently meet—

(i) The conditions for participation under medicare; or

(ii) The definitions of inpatient or outpatient hospital services under §§ 440.10 and 440.20.

(f) *Personal care services in a recipient's home.* "Personal care services in a recipient's home" means services prescribed by a physician in accordance with the recipient's and provided by an individual who is—

(1) Qualified to provide the services;

(2) Supervised by a registered nurse; and

(3) Not a member of the recipient's family.

Subpart B—Requirements and Limits Applicable to All Services

§ 440.200 Basis, purpose, and scope.

(a) This subpart implements—

(1) Section 1902(a)(10), regarding comparability of services for groups of recipients;

(2) Section 1902(a)(13) (B) and (C) of the Act, which prescribes the amount, duration, and scope of services described in 1905(a) of the Act that the State plan must provide for recipients;

(3) Section 1902(a)(22)(D), which provides for standards and methods to assure quality of services; and

(4) Section 1907 on observance of religious beliefs.

(b) The requirements and limits of this subpart apply for all services defined in subpart A of this part.

§ 440.210 Required services for the categorically needy.

A State plan must specify that, as a minimum, categorically needy recipients are provided the services as specified in §§ 440.10–440.50.

§ 440.220 Required services for the medically needy.

If the plan includes the medically needy, it must specify that the medically needy are provided, as a minimum—

(a) The medical and remedial services in §§ 440.10–440.50; or

(b) The services contained in any seven of the sections in §§ 440.10–440.160 and, if the plan includes inpatient hospital services or skilled nursing facility services, physicians' services to recipients who are patients in a hospital or skilled nursing facility, even though physician services, as defined in § 440.50, are not otherwise included for the medically needy.

§ 440.230 Sufficiency of amount, duration, and scope.

(a) The plan must specify the amount and duration of each service that it provides.

(b) Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose.

(c) (1) The medicaid agency may not deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

(2) The agency may place appropriate limits on a service based on medical necessity or on utilization control procedures.

§ 440.240 Comparability of services for groups.

Except as limited in § 440.250—

(a) The plan must provide that the services available to any categorically needy recipient under the plan are not less in amount, duration, and scope than those services available to a medically needy recipient; and

(b) The plan must provide that the services available to either the categorically or medically needy are equal in amount, duration, and scope for all recipients within the group.

§ 440.250 Limits on comparability of services.

(a) Skilled nursing facility services (§ 440.40(a)) may be limited to recipients age 21 or older.

(b) Early and periodic screening, diagnosis, and treatment (§ 440.40(b)) must be limited to recipients under age 21.

(c) Family planning services and supplies must be limited to recipients of childbearing age, including minors who can be considered sexually active and who desire the services and supplies.

(d) If covered under the plan, services to recipients in institutions for tuberculosis or mental diseases (§ 440.140) must be limited to those age 65 or older.

(e) If covered under the plan, inpatient psychiatric services (§ 440.160) must be limited to recipients age 21 or younger.

(f) If medicare benefits are made available to recipients through a buy-in agreement or payment of premiums, deductibles, cost sharing or similar charges, they may be limited to recipients who are covered by the agreement or payment.

(g) If services in addition to those offered under the plan are made available under a contract between the agency or political subdivision and an organization providing comprehensive health services, those additional services may be limited to recipients who reside in the geographic area served by the contracting organization and who elect to receive services from it.

§ 440.260 Methods and standards to assure quality of services.

The plan must include a description of methods and standards used to assure that services are of high quality.

§ 440.270 Religious objections.

(a) Except as specified in paragraph (b) of this section, the agency may not require any individual to undergo any medical service, diagnosis, or treatment or to accept any other health service provided under the plan if the individual objects, or in the case of a child, a parent or guardian objects, on religious grounds.

(b) If a physical examination is necessary to establish eligibility based on disability or blindness, the agency may not find an individual eligible for medicaid unless he undergoes the examination.

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

Sec.

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AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

§ 441.1 Purpose.

This part sets forth State plan requirements and limits on FFP for specific services defined in part 440 of this subchapter. Standards for payments for services provided in intermediate care facilities and skilled nursing facilities are set forth in part 442 of this subchapter.

Subpart A—General Provisions

§ 441.10 Basis.

This subpart is based on the following sections of the Act which state requirements and limits on the services specified or provide Secretarial authority to prescribe regulations relating to services:

(a) Sections 1902(a)(13)(A)(ii) and 1905(a)(7) for home health services (§ 441.15).

(b) Section 1905(a)(4)(C) for family planning (§ 441.20).

(c) Section 1905(a)(12) and (e) for optometric services (§ 441.30).

(d) Section 1102 for end-stage renal disease (§ 441.40).

(e) Section 1905(a) (following (a)(17)), which prohibits FFP in expenditures for certain services (§ 441.12).

§ 441.11 Continuation of FFP for institutional services.

(a) If a medicaid agency terminates or fails to renew a provider agreement for the services specified in paragraph (c) of this section because the services no longer meet the applicable definitions, FFP may be continued for a period specified in paragraph (b) of this section, only—

(1) For payment for individuals admitted to the facility before the provider agreement terminated or was not renewed; and

(2) If the agency makes reasonable efforts to transfer the individuals to another facility or to alternate care.

(b) FFP may be continued under the conditions specified in paragraph (a) of this section, for no more than 30 days from—

(1) The termination or expiration date by HCFA of the facility's provider agreement under medicare;

(2) The termination or expiration date by the agency of its provider agreement; or

(3) For a facility or program providing inpatient psychiatric services for individuals under age 21, the earlier of either—

(i) The effective date of its loss of accreditation by the Joint Commission on Accreditation of Hospitals; or

(ii) The termination by the agency of its provider agreement.

(c) FFP may be continued, as specified in this section, for the following services:

(1) Inpatient hospital services as defined in § 440.10 of this subchapter.

(2) Inpatient hospital services for individuals age 65 or older in an institution for tuberculosis or mental diseases, as defined in § 440.140 of this subchapter.

(3) Skilled nursing facility services for individuals age 21 or older, as defined in § 440.40(a) of this subchapter.

(4) Skilled nursing facility services for individuals age 65 or older in an institution for tuberculosis or mental diseases, as defined in § 440.140 of this subchapter.

(5) Intermediate care facility services, as defined in § 440.150 of this subchapter.

(6) Intermediate care facility services for individuals age 65 or older in an institution for tuberculosis or mental diseases, as defined in § 440.140 of this subchapter.

(7) Inpatient psychiatric services for individuals under age 21, as defined in § 440.160 of this subchapter.

§ 441.13 Prohibitions on FFP: Institutionalized individuals.

(a) FFP is not available in expenditures for services for—

(1) Any individual who is in a public institution, as defined in § 435.1009 of this subchapter; or

(2) Any individual who is under age 65 and is in an institution for tuberculosis or mental diseases, except an individual who is under age 22 and receiving inpatient psychiatric services under subpart D of this part.

(b) Payments to institutions for the mentally retarded or persons with related conditions and to psychiatric facilities or programs providing inpatient psychiatric services to individuals under age 21 may not include reimbursement for vocational training and educational activities.

§ 441.15 Home health services.

A State plan must provide that—

(a) Home health services include, as a minimum—

(1) Nursing services;

(2) Home health aide services; and

(3) Medical supplies, equipment, and appliances.

(b) The agency provides home health services to—

(1) Categorically needy recipients age 21 or over;

(2) Categorically needy recipients under age 21, if the plan provides skilled nursing facility services for them; individuals; and

(3) Medically needy recipients to whom skilled nursing facility services are provided under the plan.

(c) The eligibility of a recipient to receive home health services does not depend on his need for or discharge from institutional care.

§ 441.20 Family planning services.

For recipients eligible under the plan for family planning services, the plan must provide that each recipient is free from coercion or mental pressure and free to choose the method of family planning to be used.

§ 441.30 Optometric services.

The plan must provide for payment of optometric services as physician services, whether furnished by an optometrist or a physician, if—

(a) The plan does not provide for payment for services provided by an optometrist, except for eligibility determinations under §§ 435.531 and 436.531 of this subchapter, but did provide for those services at an earlier period; and

(b) The plan specifically provides that physicians' services include services an optometrist is legally authorized to perform.

§ 441.40 End-stage renal disease.

FFP in expenditures for services described in subpart A of part 440 is available for facility treatment of end-stage renal disease only if the facility has been approved by the Secretary to furnish those services under medicare. This requirement for approval of the facility does not apply under emergency conditions permitted under medicare (see § 405.1011 of this chapter).

Subpart B—Early and Periodic Screening, Diagnosis and Treatment of Individuals Under Age 21

§ 441.50 Basis and purpose.

This subpart implements sec. 1905 of the Act by prescribing State plan requirements for early and periodic screening and diagnosis of individuals under age 21 to ascertain physical and mental defects, and treatment to correct or ameliorate defects and chronic conditions found. (See 45 CFR 205.146(c) relating to reduction in FFP under AFDC for failure to provide EPSDT to individuals under age 21.)

§ 441.51 State plan requirements.

A State plan must provide that the requirements of this subpart are met with respect to early and periodic screening, diagnosis and treatment (EPSDT) of individuals under age 21, as defined in § 440.40 of this subchapter.

§ 441.52 Required services.

(a) The medicaid agency must make available, to recipients under age 21, early and periodic screening and diagnosis to determine physical and mental defects and treatment of conditions discovered within the limits in the plan on amount, duration, and scope.

(b) Subject to utilization controls it may impose, the agency must also make available, if they are not otherwise included in the plan—

(1) Treatment of visual and hearing defects, including provision of eyeglasses and hearing aids; and

(2) Dental services needed for relief of pain and infection, restoration of teeth, and maintenance of dental health.

§ 441.53 Additional services under EPSDT.

The agency may provide any other services defined in subpart A of part 440 of this subchapter under the EPSDT program to recipients under age 21, even if it does not provide those services or provides them in a lesser amount, duration, or scope to other recipients.

§ 441.54 Administration.

The agency must establish administrative procedures to—

(a) Identify available screening and diagnostic facilities;

(b) Assure that recipients under age 21 may receive services of those facilities; and

(c) Make available EPSDT services covered under the plan.

§ 441.55 Services from title V grantees.

The agency must—

(a) Identify all recipients eligible for EPSDT services, including those who are in need of medical or remedial services furnished through title V grantees; and

(b) Assure that recipients eligible for title V services are—

(1) Informed of the services; and

(2) Referred to title V grantees for services, as appropriate.

§ 441.56 Maximum utilization of existing services.

The agency must provide for agreements to assure maximum use of existing screening, diagnostic, and treatment services provided by public and voluntary agencies such as child health clinics, neighborhood health centers, and similar agencies.

Subpart C—Medicaid for Individuals Age 65 or Over in Institutions for Mental Diseases [Reserved]

Subpart D—Inpatient Psychiatric Services for Individuals Under Age 21 in Psychiatric Facilities or Programs

§ 441.150 Basis and purpose.

This subpart specifies requirements applicable if a State provides inpatient psychiatric services to individuals

under age 21, as defined in § 440.160 of this subchapter and authorized under sec. 1905 (a)(16) and (h) of the Act.

§ 441.151 General requirements.

Inpatient psychiatric services for recipients under age 21 must be provided—

(a) Under the direction of a physician;

(b) By a psychiatric facility or an inpatient program in a psychiatric facility, either of which is accredited by the Joint Commission on Accreditation of Hospitals; and

(c) Before the recipient reaches age 21 or, if the recipient was receiving the services immediately before he reached age 21, before the earlier of the following—

(1) The date he no longer requires the services; or

(2) The date he reaches age 22.

§ 441.152 Certification of need for services.

(a) A team specified in § 441.154 must certify that—

(1) Ambulatory care resources available in the community do not meet the treatment needs of the recipient;

(2) Proper treatment of the recipient's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the recipient's condition or prevent further regression so that the services will no longer be needed.

(b) The certification specified in this section and in § 441.153 satisfies the utilization control requirement for physician certification in §§ 456.60, 456.160, 456.260, and 456.360 of this subchapter.

§ 441.153 Team certifying need for services.

Certification under § 441.152 must be made by terms specified as follows:

(a) For an individual who is a recipient when admitted to a facility or program, certification must be made by an independent team that—

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably in child psychiatry; and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for medicaid while in the facility of program, the certification must be—

(1) Made by the team responsible for the plan of care as specified in § 441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (§ 441.156) within 14 days after admission.

§ 441.154 Active treatment.

Inpatient psychiatric services must involve "active treatment", which means implementation of a professionally developed and supervised individual plan of care, described in § 441.155 that is—

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the recipient's discharge from inpatient status at the earliest possible time.

§ 441.155 Individual plan of care.

(a) "Individual plan of care" means a written plan developed for each recipient in accordance with §§ 456.180–456.181, and 456.280–456.281 of this subchapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must—

(1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral and developmental aspects of the recipient's situation and reflects the need for inpatient psychiatric care;

(2) Be developed by a team of professionals specified under § 441.156 in consultation with the recipient; and his parents, legal guardians, or others in whose care he will be released after discharge;

(3) State treatment objectives;

(4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and

(5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the recipient's family, school, and community upon discharge.

(c) The plan must be reviewed every 30 days by the team specified in § 441.156 to—

(1) Determine that services being provided are or were required on an inpatient basis, and

(2) Recommend changes in the plan as indicated by the recipient's overall adjustment as an inpatient.

(d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for—

(1) Physician recertification under §§ 456.60, 456.160, 456.260, and 456.360 of this subchapter; and

(2) Establishment and periodic review of the plan of care under §§ 456.80, 456.180, 456.280, and 456.380 of this subchapter.

§ 441.156 Team developing individual plan of care.

(a) The individual plan of care under § 441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.

(b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of—

(1) Assessing the recipient's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;

(2) Assessing the potential resources of the recipient's family;

(3) Setting treatment objectives; and

(4) Prescribing therapeutic modalities to achieve the plan's objectives.

(c) The team must include, as a minimum, either—

(1) A Board-eligible or Board-certified psychiatrist;

(2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or

(3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

(d) The team must also include one of the following:

(1) A psychiatric social worker.

(2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§ 441.180 Maintenance of effort: General rule.

FFP is available only if the State maintains fiscal effort as prescribed under this subpart.

§ 441.181 Maintenance of effort: Explanation of terms and requirements.

(a) For purposes of § 441.182:

(1) The base year is the 4-quarter period ending December 31, 1971.

(2) Quarterly per capita non-Federal expenditures are expenditures for inpatient psychiatric services determined by reimbursement principles under medicare. (See Part 405, subpart D.)

(3) The number of individuals receiving inpatient psychiatric services in the current quarter means—

(i) The number of individuals receiving services for the full quarter; plus

(ii) The full quarter composite number of individuals receiving services for less than a full quarter.

(4) In determining the per capita expenditures for the base year, the medicaid agency must compute the number of individuals receiving services in a manner similar to that in paragraph (a)(3) of this section.

(5) Non-Federal expenditures means the total amount of funds expended by the State and its political subdivisions, excluding Federal funds received directly or indirectly from any source.

(6) Expenditures for the current calendar quarter exclude Federal funds received directly or indirectly from any source.

(b) As a basis for determining the correct amount of Federal payments, each State must submit estimated and actual cost data and other information necessary for this purpose in the form and at the times specified in this subchapter and by HCFA guidelines.

(c) The agency must have on file adequate records to substantiate compliance with the requirements of § 441.182 and to ensure that all necessary adjustments have been made.

(d) Facilities that did not meet the requirements of §§ 441.151–441.156 in the base year, but are providing inpatient psychiatric services under those sections in the current quarter, must be included in the maintenance of effort computation if, during the base year, they were—

(1) Providing inpatient psychiatric services for individuals under age 21; and

(2) Receiving State aid.

§ 441.182 Maintenance of effort: Computation.

(a) For expenditures for inpatient psychiatric services for individuals under age 21, in any calendar quarter, FFP is available only to the extent that the total State medicaid expenditures in the current quarter for inpatient psychiatric services and outpatient psychiatric treatment for individuals under age 21 exceed the sum of the following:

(1) The total number of individuals receiving inpatient psychiatric services in the current quarter times the average quarterly per capita non-Federal expenditures for the base year; and

(2) The average non-Federal quarterly expenditures for the base year for outpatient psychiatric services for individuals under age 21.

(b) FFP is available for 100 percent of the increase in expenditures over the base year period, but may not exceed the Federal medical assistance percentage times the expenditures under this subpart for inpatient psychiatric services for individuals under age 21.

Subpart E—Abortions

§ 441.200 Basis and purpose.

This subpart implements sec. 101 of Pub. L. 95-205 by prohibiting the use of Federal funds for abortions except under certain circumstances stated in this subpart.

§ 441.201 Definitions.

As used in this subpart—

"Law enforcement agency" means an agency, or any part of an agency, charged under applicable law with enforcement of the general penal statutes of the United States or of any State of local jurisdiction.

"Medical procedures performed upon a victim of rape or incest" means any medical service, including an abortion, performed for the purpose of preventing or terminating a pregnancy arising out of an incident of rape or incest.

"Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he practices.

"Public health service" means—

(1) An agency of the United States or of a State of local government that provides health or medical services; and

(2) A "rural health clinic," as defined under sec. 1(d)(aa)(2) of Pub. L. 95-210, 91 Stat. 1485, except that any agency or facility whose principal function is the performance of abortions is specifically excluded from this definition.

§ 441.202 General rule.

FFP is not available in expenditures for an abortion except under circumstances described in §§ 441.203 through 441.205.

§ 441.203 Life of the mother would be endangered.

FFP is available in expenditures for an abortion when a physician has found, and certified in writing to the medicaid agency, that on the basis of his professional judgment, the life of the mother would be endangered if the fetus were carried to term. The certification must contain the name and address of the patient.

§ 441.204 Severe and long-lasting damage to physical health.

(a) FFP is available in expenditures for an abortion when two physicians have found, and certified in writing to the medicaid agency, that on the basis of their professional judgment, severe and long lasting physical damage to the mother would result if the pregnancy were carried to term. The cetification must contain the name and address of the patient.

(b) At least one of the two physicians must also certify that he is not an interested physician, as defined in paragraph (c) of this section.

(c) For purposes of paragraph (b) of this section, an "interested physician" is a physician—

(1) Whose income is directly or indirectly affected by the fee paid for the performance of the abortion; or

(2) Who is the spouse of, or another relative who lives with, a physician whose income is directly or indirectly affected by the fee paid for the performance of the abortion.

§ 441.205 Rape and incest.

(a) FFP is available in expenditures for medical procedures performed upon a victim of rape or incest if the medicaid agency has received signed documention from a law enforcement agency or public health service stating—

(1) That the recipient upon whom the medical procedure was performed was reported to have been the victim of an incident of rape or incest;

(2) The date of the incident;

(3) The date of the report, which must be within 60 days of the incident;

(4) The name and address of the victim;

(5) The name and address of the individual who reported the rape or incest, if different from the victim; and

(6) That the report included the signature of the individual who reported the incident.

(b) FFP is also available in expenditures for abortions for victims of rape or incest under the circumstances described in §§ 441.203 and 441.204 without regard to the requirements of this section.

§ 441.206 Documentation needed by the medicaid agency.

FFP is not available in any expenditures for abortions or other medical procedures otherwise provided for under §§ 441.203 through 441.205 if the medicaid agency has paid without first having received the certifications and documentation specified in those sections.

§ 441.207 Drugs and devices and termination of ectopic pregnancies.

FFP is available in expenditures for drugs or devices to prevent implantation of the fertilized ovum and for medical procedures necessary for the termination of an ectopic pregnancy.

§ 441.208 Recordkeeping requirements.

Medicaid agencies must maintain copies of the certifications and docu-

mentation specified in §§ 441.203 through 441.205 for 3 years under the recordkeeping requirements at 45 CFR 74.20.

PART 442—STANDARDS FOR PAYMENT FOR SKILLED NURSING AND INTERMEDIATE CARE FACILITY SERVICES

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Subpart A—General Provisions

§ 442.1 Basis and purpose.

(a) This part states requirements for provider agreements, facility certification, and facility standards relating to the provision of skilled nursing facility and intermediate care facility services to medicaid recipients. The requirements apply to State medicaid agencies and survey agencies and to the facilities. This part is based on the following sections of the Act:

(1) Section 1902(a)(4), administrative methods for proper and efficient operation of the State plan;

(2) Section 1902(a)(27), provider agreements;

(3) Section 1902(a)(28), skilled nursing facility standards;

(4) Section 1902(a)(33)(B), State survey agency functions;

(5) Section 1905 (c) and (d), definition of intermediate care facility services;

(6) Section 1905 (f) and (i), definition of skilled nursing facility services; and

(7) Section 1910, participation of medicare-certified skilled nursing facilities in medicaid.

(b) Section 431.610 of this subchapter contains requirements for designating the State licensing agency to survey these facilities and for certain survey agency responsibilities.

§ 442.2 Terms.

In this part—

"Facility" refers to a skilled nursing facility (SNF), an intermediate care facility (ICF), and an intermediate care facility for the mentally retarded or persons with related conditions (ICF/MR). Except where otherwise specified, "ICF" refers to both an ICF and an ICF/MR.

"Facility", and any specific type of facility referred to, may include a distinct part of a facility as specified in § 440.40 or § 440.150 of this subchapter.

Subpart B—Provider Agreements

§ 442.10 State plan requirement.

A State plan must provide that requirements of this subpart are met.

§ 442.12 Provider agreement: General requirements.

(a) A medicaid agency may not execute a provider agreement with a facility for SNF or ICF services nor make medicaid payments to a facility for those services unless the Secretary or the State survey agency has certified the facility under this part to provide those services. (See § 442.101 for certification by the Secretary or by the State survey agency. This certification requirement does not apply with respect to Christian Science sanitoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

(b) The effective date of an agreement may not be earlier than the date of certification.

(c) An agreement must be in accordance with the certification provisions set by the Secretary or the survey agency under subpart C of this part.

(d) If the medicaid agency has adequate documentation showing good cause, it may refuse to execute an agreement, or may cancel an agreement, with a certified facility.

§ 442.15 Duration of agreement.

(a) Except as specified under § 442.16, the duration of an agreement may not exceed 12 months.

(b) The agreement must be for the same duration as the certification period set by the survey agency. However, if the medicaid agency has adequate documentation showing good cause, it may make an agreement for less than this period.

(c) FFP is available for services provided by a facility for up to 30 days after its agreement expires or terminates under the conditions specified in § 441.11 of this subchapter.

§ 442.16 Extension of agreement.

A medicaid agency may extend a provider agreement for up to 2 months beyond its original expiration date if it receives written notice from the survey agency, before the expiration date of the agreement, that extension will not jeopardize the patients' health and safety, and—

(a) Is needed to prevent irreparable harm to the facility or hardship to the recipients in the facility; or

(b) Is needed because it is impracticable to determine, before the expiration date, whether the facility meets certification standards.

§ 442.20 Additional requirements for agreements with SNF's participating in medicare.

(a) The medicaid agency's agreement with a SNF participating in medicare must—

(1) Provide for the same terms and conditions as medicare certification; and

(2) Be for the same duration as the medicare certification.

(b) When the Secretary notifies the medicaid agency that a medicare agreement with a SNF has been terminated, the agency must terminate its medicaid agreement with that SNF.

(c) If the medicaid agency has terminated an agreement under paragraph (b) of this section, it may not make another agreement with that SNF until—

(1) The conditions causing the termination are removed; and

(2) The SNF provides reasonable assurance to the survey agency that the conditions will not recur.

§ 442.30 Agreement as evidence of certification.

(a) Under §§ 440.40(a) and 440.150 of this subchapter, FFP is available in expenditures for SNF and ICF service only if the facility has been certified as meeting the requirements for medicaid participation, as evidenced by a provider agreement executed under this part. An agreement is not valid evidence that a facility has met those requirements if the Administrator determines that—

(1) The survey agency failed to apply the applicable certification standards required under subpart D, E, F, or G of this part;

(2) The survey agency failed to follow the rules and procedures for certification set forth in subpart C of this part and § 431.610 of this subchapter;

(3) The survey agency failed to perform any of the functions specified in § 431.610(g) of this subchapter relating to evaluating and acting on information about the facility and inspecting the facility;

(4) The survey agency failed to use the Federal standards and the forms, methods, and procedures required under § 431.610(f)(1) for determining qualifications of providers; or

(5) The agreement's terms and conditions do not meet the requirements of this subpart.

(b) The Administrator will make the determination under paragraph (a) of this section through onsite surveys, other Federal reviews, State certification records, or reports he may require from the medicaid or survey agency.

(c) If the Administrator disallows a State's claim for FFP because of a determination under paragraph (a) of this section, the State is entitled upon request to reconsideration of the disallowance under 45 CFR Part 16.

Subpart C—Certification of SNF's and ICF's

§ 442.100 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

§ 442.101 Obtaining certification.

(a) This section states the requirements for obtaining notice of a facility's certification before a medicaid agency executes a provider agreement under § 442.12.

(b) The agency must obtain notice of certification from the Secretary for—

(1) A facility located on an Indian reservation; and

(2) A SNF that has been certified for medicare payments.

(c) The agency must obtain notice of certification from the survey agency for all other facilities.

(d) The notice must state that the facility—

(1) Meets the applicable requirements under subpart D, E, F, or G of this part, except for waivers or variations granted by the Secretary or the survey agency under those subparts; or

(2) Has been certified with provision for correcting deficiencies in meeting those requirements, under the conditions of this subpart.

(e) For purposes of certification of facilities under this subpart, a waiver of standards is not a deficiency.

§ 442.105 Certification with deficiencies: General provisions.

If a survey agency finds a facility deficient in meeting the standards specified under subpart D, E, F, or G of this part, the agency may certify the facility for medicaid purposes under the following conditions:

(a) The agency finds that the facility's deficiencies, individually or in combination, do not jeopardize the patient's health and safety, nor seriously limit the facility's capacity to give adequate care. The agency must maintain a written justification of these findings.

(b) The agency finds acceptable the facility's written plan for correcting the deficiencies.

(c) If a facility was previously certified with a deficiency and has a different deficiency at the time of the next survey, the agency documents that the facility—

(1) Was unable to stay in compliance with the standard for reasons beyond its control, or despite intensive efforts to comply; and

(2) Is making the best use of its resources to furnish adequate care.

(d) If a facility has the same deficiency it had under the prior certification, the agency documents that the facility—

(1) Did achieve compliance with the standard at some time during the prior certification period;

(2) Made a good faith effort, as judged by the survey agency, to stay in compliance; and

(3) Again became out of compliance for reasons beyond its control.

(e) If an ICF or ICF/MR has a deficiency of the types specified in §§ 442.112 or 442.113 that requires a plan of correction extending beyond 12 months, the agency documents that the conditions of those sections are met.

§ 442.110 Certification period: General provisions.

(a) A survey agency may certify a facility that fully meets applicable requirements for up to 12 months.

(b) The survey agency may notify the medicaid agency that the term of a provider agreement may be extended up to 2 months after the expiration date of the agreement under the conditions specified in § 442.16.

§ 442.111 Certification period: Facilities with deficiencies.

(a) Facilities with deficiencies may be certified under § 442.105 for the period specified in either paragraph (b) or (c) of this section. However, ICF's with deficiencies that may require more than 12 months to correct may be certified under §§ 442.112 and 442.113.

(b) The survey agency may certify a facility for a period that ends no later than 60 days after the last day specified in the plan for correcting deficiencies. The certification period must not exceed 12 months, including the period allowed for corrections.

(c) The survey agency may certify a facility for up to 12 months with a condition that the certification will be automatically canceled on a specified date within the certification period unless—

(1) The survey agency finds that all deficiencies have been satisfactorily corrected; or

(2) The survey agency finds and notifies the medicaid agency that the facility has made substantial progress in correcting the deficiencies and has a new plan for correction that is acceptable.

The automatic cancellation date must be no later than 60 days after the last day specified in the plan for correction of deficiencies under § 442.105.

§ 442.112 Extended period for correcting deficiencies: ICF's other than ICF's/MR; environment, sanitation, and Life Safety Code deficiencies.

(a) *Scope.* This section applies to ICF's other than ICF's/MR that are deficient in meeting requirements for—

(1) Environment and sanitation (§§ 442.324–442.330); or

(2) Life Safety Code (§§ 442.321–442.323).

(b) *Certification period.* The survey agency may certify an ICF other than an ICF/MR under § 442.105 for up to 12 months even though the facility has deficiencies that may take up to 2 years after the first certification of the facility to correct, if the conditions in this section are met.

(c) *Written plan for correction.* The ICF must submit a written plan for correcting the deficiencies that—

(1) Specifies the steps the facility will take to correct each deficiency;

(2) Specifies a timetable for taking each of those steps and a date for completion of correction of each deficiency that is not later than 2 years after the date the facility is first certified; and

(3) Is acceptable to the survey agency.

(d) *Feasibility of plan.* The survey agency must find that the facility can—

(1) Potentially meet the requirements in which it is deficient by taking the steps specified in the plan for correction; and

(2) Correct each deficiency by the date specified in the plan for correction.

(e) *Progress in meeting correction plan.* Within each 6-month period after acceptance of the plan for correction, the survey agency must find, and record in the survey record, that the facility has made substantial progress in meeting its plan for correction. These findings must be based on onsite surveys by qualified surveyors. The survey agency must support these findings by placing signed contracts, work orders, or other documents in the survey record.

(f) *State fire safety and sanitation requirements.* The survey agency must find that, during the period allowed for corrections, the facility meets State fire safety and sanitation codes and regulations.

§ 442.113 Extended period for correcting deficiencies: ICF's/MR; Life Safety Code and living/dining/therapy area deficiencies.

(a) *Scope.* This section applies to ICF's/MR that are deficient in meeting requirements for—

(1) Life Safety Code (§§ 442.507-442.509);

(2) Living units (§§ 442.447(a) (1), (2), (4), (5), (b), (c), 442.448(d), 442.449 (a), (b), 442.450(a)(2), 442.451(a), 442.452, 442.453);

(3) Dining rooms (§ 442.471(a)-(c)); or

(4) Therapy areas (§ 442.488(e)).

(b) *Certification period.* The survey agency may certify an ICF/MR under § 442.105 for up to 12 months even though the deficiencies listed in paragraph (a) of this section may take more than 12 months to correct, if the conditions in this section and § 442.115 are met.

(c) *Written plan for correction.* Before certifying an ICF/MR under this section, the survey agency must approve, in writing, the ICF/MR's written plan for correcting those deficiencies. The plan must—

(1) State the extent to which the ICF/MR complies with the requirements it does not fully meet;

(2) Specify the steps the ICF/MR will take to correct the deficiencies;

(3) Specify a timetable for taking each of those steps and a date for completion of corrections;

(4) For a public ICF/MR, be approved by the State or political subdivision that has jurisdiction over its operation (A public facility is defined in § 435.1009 of this subchapter as one that is the "responsibility of a governmental unit or over which a governmental unit exercises administrative control."); and

(5) Meet the conditions of § 442.115.

(d) *Progress in meeting correction plan.* Within each 6-month period after initial approval of the plan, the survey agency must find, and record in the survey record, that the ICF/MR has made substantial progress in meeting the plan for correction. These findings must be based on onsite surveys by qualified surveyors. The survey agency must support these findings by placing signed contracts, work orders, or other documentation in the survey record.

(e) *State fire safety and sanitation requirements.* The survey agency must find that, during the period allowed for corrections, the ICF/MR meets the State fire safety and sanitation codes and regulations.

§ 442.115 Correction plans.

(a) The ICF/MR's plan required by § 442.113 must provide for completion of corrections by July 18, 1980, or, if authorized by the Secretary under paragraph (b) of this section, by July 18, 1982.

(b) If, at the time of the first survey of the ICF/MR after July 17, 1977, it is unable to develop a plan to complete corrections by July 18, 1980, the survey agency may request the Secretary to authorize approval of a plan to complete them by July 18, 1982. The Secretary will authorize this approval for each deficiency if he determines that time beyond July 18, 1977, is needed—

(1) As a practical matter to complete the corrections;

(2) To prevent unreasonable hardship to the ICF/MR; and

(3) To insure continued care for recipients served by the ICF/MR.

(c) If the plan provides for correction through structural change or renovation, it must—

(1) Contain a timetable showing the corrective steps and their completion dates;

(2) Specify the structural change or renovation; and

(3) Document that sufficient financial resources are available to complete the change or renovation on schedule.

(d) If the plan provides for correction by phasing out part or all of the ICF/MR, it must—

(1) Contain a timetable showing the buildings or units to be closed and describing the steps for phasing them out;

(2) Describe the methods that insure the recipients' health and safety until the building or unit is closed; and

(3) Provide that no new recipients will be admitted to the building or unit after the plan has been approved.

Subpart D—Skilled Nursing Facility Requirements

§ 442.200 Purpose.

This subpart specifies the requirements that a SNF must meet to obtain certification from the Secretary or the State survey agency as a qualified medicaid provider of SNF services.

§ 442.201 State licensing standards.

(a) A SNF must meet State nursing home licensing standards. However, if a SNF that formerly met State licensing standards does not currently meet them, it may continue to receive medicaid payments as a qualified provider during a period specified by the responsible licensing authority if, during that period, the SNF takes the steps needed to again meet the standards.

(b) For purposes of this subpart, the fact that a SNF actually holds a current license is immaterial if the responsible State licensing authority determines that, in fact, the standards are not met.

(c) In accordance with § 431.110 of this subchapter, an Indian Health Service SNF must meet State licensing standards although it need not obtain a license. In making this determination, the licensing authority may not take into account an absence of licensure of any staff member of the facility.

§ 442.202 Federal definitions and standards.

The SNF must meet—

(a) The definition of a "skilled nursing facility" in § 440.40(a) of this subchapter;

(b) The definition in section 1861(j) of the Act; and

(c) The standards specified in part 405, subpart K, of this chapter: Conditions of participation; skilled nursing facilities, except for provisions waived under that subpart or accepted by the Secretary or the State survey agency under a plan of correction as specified in subpart B of this part. Provisions that may be waived under part 405, subpart K, include:

(1) Building accessibility, § 405.1134(c);

(2) Patient room and toilet facilities, § 405.1134(e); and

(3) Utilization review, § 405.1137, if authorized under §§ 456.501-456.508 of this subchapter.

Subpart E—Intermediate Care Facility Requirements; All Facilities

§ 442.250 Purpose.

This subpart specifies the requirements that an ICF must meet to obtain certification from the State survey agency as a qualified provider of ICF services.

§ 442.251 State licensing standards.

(a) Except as provided in paragraph (b), an ICF must meet standards for a State license to provide, on a regular basis, health-related care and services to individuals who do not require hospital or SNF care, but whose mental or physical condition requires services—

(1) Above the level of room and board; and

(2) That can be provided only by an institution.

(b) An ICF that formerly met State licensing standards but does not currently meet them may continue to receive medicaid payments as a qualified provider during a period specified by the State authority responsible for licensing the facility if, during that period, the ICF takes the steps needed to again meet the standards.

(c) An ICF operated by a government agency must meet the licensing standards that apply to the same type of facility operated under any other ownership.

(d) In accordance with § 431.110 of this subchapter, an Indian Health Service ICF must meet State licensing standards although it need not obtain a license. In making this determination, the licensing authority may not take into account an absense of licensure of any staff member of the facility.

§ 442.252 State safety and sanitation standards.

An ICF must meet State safety and sanitation standards for nursing homes.

§ 442.253 Federal definition and standards.

(a) An ICF other than an ICF/MR must meet the definition in § 440.150 of this subchapter and the standards specified in this subpart and subpart F of this part, except for provisions waived or accepted under plans of corrections as specified in subpart C of this part.

(b) An ICF/MR must meet the definition in § 440.150 of this subchapter and the standards specified in this subpart and subpart G of this part, except for provisions waived or accepted under plans of correction as specified in subpart C of this part.

§ 442.254 Standards for hospitals and SNF's providing ICF services.

(a) If a hospital or SNF participating in medicare or medicaid is also a provider of ICF services other than ICF/MR services, it must meet the following ICF standards:

(1) 442.304, resident services director.

(2) 442.317 (a), (b), agreements with outside resources for institutional services.

(3) 442.319, plan of care.

(4) 442.320, resident financial records.

(5) 442.324 (b), handrails.

(6) 442.338 through 442.342, health services.

(7) 442.343, rehabilitative services.

(8) 442.344, social services.

(9) 442.345, activities program.

(10) 442.346, physician services.

(b) If a hospital or SNF participating in medicare or medicaid is also a provider of ICF/MR services, it must meet the standards in subpart G of this part.

Subpart F—Standards for Intermediate Care Facilities Other Than Facilities for the Mentally Retarded

§ 442.300 Basis, purpose, and scope.

This subpart implements section 1905(c) of the Act, which gives the Secretary authority to prescribe standards for care, safety, and sanitation in intermidiate care facilities. It applies to ICF's other than ICF's/MR.

Administration

§ 442.301 Methods of administration.

An ICF must have methods of administrative management that insure that it meets the requirements of §§ 442.302 through 442.315.

442.302 Staffing.

The ICF must have staff on duty 24 hours a day sufficient in number and qualifications to carry out the policies, responsibilities, and programs of the ICF.

§ 442.303 Administrator.

(a) The ICF must have an administrator who is—

(1) A nursing home administrator with a current State license; or

(2) A hospital administrator, if the ICF is a hospital qualifying as an intermediate care facility.

(b) The administrator's responsibilities must include—

(1) Managing the ICF; and

(2) Implementing established policies and procedures.

§ 442.304 Resident services director.

(a) The ICF must designate the administrator or a professional staff member as resident services director.

(b) The duties of the resident services director must include coordinating and monitoring each resident's overall plan of care.

§ 442.305 Written policies and procedures: General requirements.

The ICF must have written policies and procedures that—

(a) Govern all services provided by the ICF; and

(b) Are available to the staff, residents, members of the family and legal representatives of residents, and the public.

§ 442.306 Written policies and procedures: Admission.

The ICF must have written policies and procedures that insure that it admits as residents only those individuals whose needs can be met—

(a) By the ICF itself;

(b) By the ICF in cooperation with community resources; or

(c) By the ICF in cooperation with other providers of care affiliated with or under contract to the ICF.

§ 442.307 Written policies and procedures: Transfer and discharge.

The ICF must have written policies and procedures that insure that—

(a) It transfers a resident promptly to a hospital, skilled nursing facility, or other appropriate facility, when a change occurs in the resident's physical or mental condition that requires care or service that the ICF cannot adequately provide; and

(b) Except in an emergency, it—

(1) Consults the resident, his next of kin, the attending physician, and the responsible agency, if any, at least 5 days before a transfer or discharge; and

(2) Uses casework services or other means to insure that adequate arrangements are made to meet the resident's needs through other resources.

§ 442.308 Written policies and procedures: Chemical and physical restraints.

The ICF must have written policies and procedures that—

(a) Define the uses of chemical and physical restraints;

(b) Identify the professional personnel who may, under § 442.311(h), authorize use of these restraints in emergencies; and

(c) describe the procedures for monitoring and controlling the use of these restraints.

§ 442.309 Written policies and procedures: Resident complaints and recommendations.

The ICF must have written policies and procedures that—

(a) Describe the procedures the ICF uses to receive complaints and recommendations from its residents; and

(b) Insure that the ICF responds to these complaints and recommendations.

§ 442.310 Written policies and procedures: Resident records.

The ICF must have written policies and procedures governing access to, duplication of, and dissemination of information from the resident's record.

§ 442.311 Written policies and procedures: Residents' bill of rights.

The ICF must have written policies and procedures that insure the following rights for each resident: (a) *Information.* (1) Each resident must be fully informed, before or at the time of admission, of his rights and and responsibilities and of all rules governing resident conduct.

(2) If the ICF amends its policies on residents' rights and responsibilities and its rules governing conduct, each resident in the ICF at that time must be informed.

(3) Each resident must acknowledge in writing receipt of the information and any amendments to it.

(4) Each resident must be fully informed in writing of all services available in the ICF and of the charges for these services including any charges for services not paid for by medicaid or not included in the ICF's basic rate per day. The ICF must provide this information either before or at the time of admission and on a continuing basis as changes occur in services or charges during the resident's stay.

(b) *Medical condition and treatment.* (1) Each resident must—

(i) Be fully informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated;

(ii) Be given the opportunity to participate in planning his total care and medical treatment;

(iii) Be given the opportunity to refuse treatment; and

(iv) Give informed, written consent before participating in experimental research.

(2) If the physician decides that informing the resident of his health and medical condition is medically contraindicated, the physician must document this decision in the resident's record.

(c) *Transfer and discharge.* Each resident must be transferred or discharged only for—

(1) Medical reasons;

(2) His welfare or that of the other residents; or

(3) Nonpayment except as prohibited by the medicaid program.

(d) *Exercising rights.* Each resident must be—

(1) Encouraged and assisted to exercise his rights as a resident of the ICF and as a citizen; and

(2) Allowed to submit complaints or recommendations concerning the policies and services of the ICF to staff or to outside representatives of the resident's choice or both, free from restraint, interference, coercion, discrimination, or reprisal.

(e) *Financial affairs.* Each resident must be allowed to manage his personal financial affairs. If a resident requests assistance from the ICF in managing his personal financial affairs—

(1) The request must be in writing; and

(2) The ICF must comply with the recordkeeping requirements of § 442.320.

(f) *Freedom from abuse and restraints.* (1) Each resident must be free from mental and physical abuse.

(2) Each resident must be free from chemical and physical restraints unless the restraints are—

(i) Authorized by a physician in writing for a specified period of time; or

(ii) Used in an emergency under the following conditions:

(A) The use is necessary to protect the resident from injuring himself or others.

(B) The use is authorized by a professional staff member identified in the written policies and procedures of the facility as having the authority to do so.

(C) The use is reported promptly to the resident's physician by that staff member.

(g) *Privacy.* (1) Each resident must be treated with consideration, respect, and full recognition of his or her dignity and individuality.

(2) Each resident must be given privacy during treatment and care of personal needs.

(3) Each resident's records, including information in an automatic data bank, must be treated confidentially.

(4) Each resident must give written consent before the ICF may release information from his record to someone not otherwise authorized by law to receive it.

(5) A married resident must be given privacy during visits by his spouse.

(6) If both husband and wife are residents of the ICF, they must be permitted to share a room.

(h) *Work.* No resident may be required to perform services for the ICF.

(i) *Freedom of association and correspondence.* Each resident must be allowed to—

(1) Communicate, associate, and meet privately with individuals of his choice, unless this infringes on the rights of another resident; and

(2) Send and receive personal mail unopened.

(j) *Activities.* Each resident must be allowed to participate in social, religious, and community group activities.

(k) *Personal possessions.* Each resident must be allowed to retain and use his personal possessions and clothing as space permits.

§ 442.312 Written policies and procedures: Delegation of rights and responsibilities.

(a) The ICF must have written policies and procedures that provide that all rights and rsponsibilities of a resident pass to the resident's guardian, next of kin, or sponsoring agency or agencies if the resident—

(1) Is adjudicated incompetent under State law; or

(2) Is determined by his physician to be incapable of understanding his rights and responsibilities.

(b) If the resident is determined to be incapable of understanding his rights and responsibilities, the physician who made the determination must record the specific reason in the resident's record.

§ 442.313 Emergencies.

The ICF must—

(a) Have a written plan for staff and residents to follow in case of an emergency such as a fire or an explosion and rehearse the plan regularly; and

(b) Have written procedures for the staff to follow in case of an emergency involving a resident. These emergency procedures must include directions for—

(1) Caring for the resident;

(2) Notifying the attending physician and other individuals responsible for the resident; and

(3) Arranging for transportation, hospitalization, or other appropriate services.

§ 442.314 Staff training programs.

The ICF must—

(a) Conduct an orientation program for all new employees that includes a review of all its policies;

(b) Plan and conduct an inservice staff development program for all personnel to assist them in developing and improving their skills; and

(c) Maintain a record of each orientation and staff development program it conducts. The record must include the content of the program and the names of the participants.

§ 442.315 Health and safety laws.

The ICF must meet all Federal, State, and local laws, regulations, and codes pertaining to health and safety, such as provisions regulating—

(a) Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances;

(b) Construction, maintenance, and equipment for the ICF;

(c) Sanitation;

(d) Communicable and reportable diseases; and

(e) Post mortem procedures.

§ 442.316 Transfer agreements.

(a) Except as provided in paragraph (b) of this section, the ICF must have in effect a transfer agreement with one or more hospitals sufficiently close by to make feasible the prompt transfer of the resident and his records to the hospital and to support a working arrangement between the ICF and the hospital for providing inpatient hospital services to residents when needed.

(b) If the survey agency finds that the ICF tried in good faith to enter into an agreement but could not, the ICF will be considered to meet the requirements of paragraph (a) as long as the survey agency finds that it is in the public interest and essential to assuring ICF services for eligible individuals in the community.

§ 442.317 Arrangements with outside resources.

(a) If the ICF does not employ a qualified professional to furnish a required institutional service, it must have in effect a written agreement with a qualified professional outside the ICF to furnish the required service.

(b) The agreement must—

(1) Contain the responsibilities, functions, objectives, and other terms agreed to by the ICF and the qualified professional; and

(2) Be signed by the administrator or his representative and by the qualified professional.

(c) The ICF must maintain effective arrangements with outside resources for promptly providing medial and remedical services required by a resident but not regularly provided within the ICF.

§ 442.318 Resident record system.

(a) The ICF must maintain an organized resident record system that contains a record for each resident.

(b) The ICF must make resident records available to staff directly involved with the resident and to appropriate representatives of the medicaid agency.

(c) Each resident's record must contain—

(1) Identification information;

(2) Admission information, including the medical and social history of the resident;

(3) An overall plan of care as described in § 442.319;

(4) Copies of the initial and periodic examinations, evaluations, progress notes, all plans of care with subsequent changes, and discharge summaries;

(5) Description of treatments and services provided and medications administered; and

(6) All indications of illness or injury including the date, time, and action taken regarding each.

(d) The ICF must protect the resident records against destruction, loss, and unauthorized use.

(e) The ICF must keep a resident's record for at least 3 years after the date the resident is discharged.

§ 442.319 Overall plan of care.

The overall plan of care required by § 442.318 must—

(a) Set the goals to be accomplished by the resident;

(b) Prescribe an integrated program of activities, therapies, and treatments designed to help each resident achieve his goals; and

(c) Indicate which professional service or individual is responsible for each service prescribed in the plan.

§ 442.320 Resident financial records.

(a) The ICF must maintain a current, written financial record for each resident that includes written receipts for—

(1) All personal possessions and funds received by or deposited with the ICF; and

(2) All disbursements made to or for the resident.

(b) The financial record must be available to the resident and his family.

SAFETY STANDARDS

§ 442.321 Fire protection.

(a) Except as provided in §§ 442.322 and 442.323 and paragraph (b) of this section, the ICF must meet the provisions of the Life Safety Code of the National Fire Protection Association, 1967 edition, that apply to institutional occupancies.

(b) If the Secretary finds that the State has a fire and safety code imposed by State law that adequately protects residents in ICF's, the State survey agency may apply the State code for the purposes of medicaid certification instead of the Life Safety Code.

§ 442.322 Fire protection: Exception for smaller ICF's.

The State survey agency may apply the lodgings or rooming houses section of the residential occupancy requirements of the Life Safety Code of the National Fire Protection Association, 1967 edition, instead of the institutional occupancy provisions required by § 442.321 to an ICF that has 15 beds or less if the ICF is primarily engaged in the treatment of alcoholism and drug abuse and a physician certifies that each resident is—

(a) Ambulatory;

(b) Engaged in an active program for rehabilitation designed to and reasonably expected to lead to independent living; and

(c) Capable of following directions and taking appropriate action for self-preservation under emergency conditions.

§ 442.323 Fire protection: Waivers.

(a) The State survey agency may waive specific provisions of the Life Safety Code required by § 442.321, for as long as it considers appropriate, if—

(1) The waiver would not adversely affect the health and safety of the residents;

(2) Rigid application of specific provisions of the Code would result in unreasonable hardship for the ICF as determined under guidelines contained in the HCFA Long Term Care Manual; and

(3) The waiver is granted in accordance with criteria contained in the Long Term Care Manual.

(b) If the State survey agency waives provisions of the Code for an existing building of two or more stories that is not built of at least 2-hour fire-resistive construction, the ICF may not house a blind, nonambulatory, or physically handicapped resident above the street-level floor unless it is built of—

(1) One-hour protected, noncombustible construction as defined in National Fire Protection Association Standard No. 220;

(2) Fully sprinklered, 1-hour protected, ordinary construction; or

(3) Fully sprinklered, 1-hour protected, wood frame construction.

ENVIRONMENTAL AND SANITATION STANDARDS

§ 442.324 Resident living areas.

The ICF must—

(a) Design and equip the resident living areas for the comfort and privacy of each resident; and

(b) Have handrails that are firmly attached to the walls in all corridors used by residents.

§ 442.325 Residents' rooms.

(a) Each resident room must—

(1) Be equipped with or conveniently located near toilet and bathing facilities;

(2) Be at or above grade level;

(3) Contain a suitable bed for each resident and other appropriate furniture;

(4) Have closet space that provides security and privacy for clothing and personal belongings;

(5) Contain no more than four beds;

(6) Measure at least 100 square feet for a single-resident room or 80 square feet for each resident for a multiresident room; and

(7) Be equipped with a device for calling the staff member on duty.

(b) For an existing building, the State survey agency may waive the space and occupancy requirements of paragraphs (a) (5) and (6) of this section for as long as it is considered appropriate if it finds that—

(1) The requirements would result in unreasonable hardship on the ICF if strictly enforced; and

(2) The waiver serves the particular needs of the residents and does not adversely affect their health and safety.

§ 442.326 Bathroom facilities.

The ICF must—

(a) Have toilet and bathing facilities that are located in or near residents' rooms and are appropriate in number, size, and design to meet the needs of the residents;

(b) Provide an adequate supply of hot water at all times for resident use; and

(c) Have plumbing fixtures with control valves that automatically regulate the temperature of the hot water used by residents.

§ 442.327 Linen supplies.

The ICF must have available at all times enough linen for the proper care and comfort of the residents and have clean linen on each bed.

§ 442.328 Therapy and isolation areas.

(a) The ICF's therapy area must be of sufficient size and appropriate design to—

(1) Accommodate the necessary equipment;

(2) Conduct an examination; and

(3) Provide treatment.

(b) The ICF must make provision for isolating residents with infectious diseases.

§ 442.329 Dining, recreation, and social rooms.

(a) The ICF must provide one or more areas, not used for corridor traffic, for dining, recreation, and social activities.

(b) A multipurpose room may be used if it is large enough to accommodate all of the activities without their interfering with each other.

§ 442.330 Building accessibility and use.

(a) The ICF must—

(1) Be accessible to and usable by all residents, personnel, and the public, including individuals with disabilities; and

(2) Meet the requirements of American National Standards Institute (ANSI) standard No. A117.1 (1961), American standard specifications for making building and facilities accessible to and usable by the physically handicapped.

(b) The State survey agency may waive, for as long as it considers appropriate, provisions of ANSI standard No. A117.1 (1961) if—

(1) The construction plans for the ICF or a part of it were approved and stamped by the responsible State agency before March 18, 1974;

(2) The provisions would result in unreasonable hardship on the ICF if strictly enforced; and

(3) The waiver does not adversely affect the health and safety of the residents.

Meal Service

§ 442.331 Meal service.

The ICF must—

(a) Serve at least three meals or their equivalent each day at regular times, with not more than 14 hours between a substantial evening meal and breakfast;

(b) Procure, store, prepare, distribute, and serve all food under sanitary conditions; and

(c) Provide special eating equipment and utensils for residents who need them.

§ 442.332 Menu planning and supervision.

(a) The ICF must have a staff member trained or experienced in food management or nutrition who is responsible for—

(1) Planning menus that meet the nutritional needs of each resident, following the orders of the resident's physician and, to the extent medically possible, the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences (Recommended Dietary Allowances (8th ed., 1974) is available from the Printing and Publications Office, National Academy of Sciences, Washington, D.C. 20418); and

(2) Supervising the meal preparation and service to insure that the menu plan is followed.

(b) If the ICF has residents who require medically prescribed special diets, the ICF must—

(1) Have the menus for those residents planned by a professionally qualified dietitian, or reviewed and approved by the attending physician; and

(2) Supervise the preparation and serving of meals to insure that the resident accepts the special diet.

(c) The ICF must keep for 30 days a record of each menu as served.

Medications

§ 442.333 Licensed pharmacist.

The ICF must either—

(a) Employ a licensed pharmacist; or

(b) Have a formal arrangement with a licensed pharmacist to advise the ICF on ordering, storage, administration, disposal, and recordkeeping of drugs and biologicals.

§ 442.334 Orders for medications.

(a) The resident's attending or staff physician must order all medications for the resident.

(b) The order may be either oral or written.

(c) If the order is oral—

(1) The physician must give it only to a licensed nurse, pharmacist, or another physician; and

(2) The individual receiving the order must record and sign it immediately and have the attending physician sign it in a manner consistent with good medical practice.

§ 442.335 Methods to control medication dosage.

The ICF must have written policies and procedures for controlling medication dosage, by automatic stop orders or other methods, when the physician does not include in the order a specific limit on the time or number of doses. These procedures must include notice to the attending physician that the medication is being stopped as of a certain date or after a certain number of doses.

§ 442.336 Review of medications.

(a) A registered nurse must review medications monthly for each resident and notify the physician if changes are appropriate.

(b) The attending or staff physician must review the medications quarterly.

§ 442.337 Administering medications.

(a) Before administering any medication to a resident, a staff member must complete a State-approved training program in medication administration.

(b) The ICF may allow a resident to give himself a medication only if the attending physician gives permission.

Health Services

§ 442.338 Health services.

(a) The ICF must provide for each resident health services that—

(1) Meet the requirements of §§ 442.339 through 442.342; and

(2) Include treatment, medications, diet, and any other health service prescribed or planned for the resident.

(b) The ICF must provide these services 24 hours a day.

§ 442.339 Supervision.

(a) The ICF must have a registered nurse or a licensed practical or vocational nurse to supervise the ICF's health services full time, 7 days a week, on the day shift.

(b) The nurse must have a current license to practice in the State.

(c) If the ICF employs a licensed practical or vocational nurse to supervise health services, the ICF must have a formal contract with a registered nurse to consult with the licensed practical or vocational nurse at regular intervals, but not less than 4 hours each week.

(d) To be qualified to serve as a health services supervisor, a licensed practical or vocational nurse must—

(1) Be a graduate of a State-approved school of practical nursing;

(2) Have education or other training that the State authority responsible for licensing practical nurses considers equal to graduation from a State-approved school of practical nursing; or

(3) Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.

(e) The ICF may employ as charge nurse an individual who is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse if—

(1) The individual has completed a training program to get the license that included at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing; and

(2) The State agency responsible for licensing the individual submits a report to the medicaid agency comparing State licensed practical nurse or vocational nurse course requirements with those for the program completed by the individual.

§ 442.340 24-hour staffing.

The ICF must have responsible staff members on duty and awake 24 hours a day to take prompt, appropriate action in case of injury, illness, fire, or other emergency.

§ 442.341 Individual health care plan.

(a) Appropriate staff must develop and implement a written health care plan for each resident according to the instructions of the attending or staff physician.

(b) The plan must be reviewed and revised as needed but at least quarterly.

§ 442.342 Nursing care.

The ICF must provide nursing care for each resident as needed, including restorative nursing care that enables each resident to achieve and maintain the highest possible degree of function, self-care, and independence.

OTHER SERVICES

§ 442.343 Rehabilitative services.

(a) The ICF must provide rehabilitative services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The rehabilitative services must be designed to—

(1) Maintain and improve the resident's ability to function independently;

(2) Prevent, as much as possible, advancement of progressive disabilities; and

(3) Restore maximum function.

(d) The rehabilitative services must be provided by—

(1) Qualified therapists or qualified assistants, as defined in 42 CFR 405.1101 (m), (n), (q), (r), and (t), in accordance with accepted professional practices; or

(2) Other supportive personnel under appropriate supervision.

(e) The rehabilitative services must be provided under a written plan of care that is—

(1) Developed in consultation with the attending physician and, if necessary, an appropriate therapist; and

(2) Based on the attending physician's orders and an assessment of the resident's needs.

(f) The resident's progress under the plan must be reviewed regularly and the plan must be changed as necessary.

§ 442.344 Social services.

(a) The ICF must provide social services for each resident as needed.

(b) The ICF must either provide these services itself or arrange for them with qualified outside resources.

(c) The ICF must designate one staff member, qualified by training or experience, to be responsible for—

(1) Arranging for social services; and

(2) Integrating social services with other elements of the plan of care.

(d) These services must be provided under a written plan of care that is—

(1) Placed in the resident's record; and

(2) Evaluated periodically in conjunction with the resident's overall plan of care.

§ 442.345 Activities program.

The ICF must—

(a) Provide an activities program designed to encourage each resident to maintain normal activity and to return to self-care;

(b) Designate one staff member, qualified by training or experience in directing group activity, to be responsible for it;

(c) Have a plan for independent and group activities for each resident that is—

(1) Developed according to his needs and interests;

(2) Incorporated in his overall plan of care;

(3) Reviewed, with his participation, at least quarterly; and

(4) Changed as needed.

(d) Provide adequate recreation areas with sufficient equipment and materials to support the program.

§ 442.346 Physician services.

(a) The ICF must have policies and procedures to insure that the health care of each resident is under the continuing supervision of a physician.

(b) The physician must see the resident whenever necessary but at least once every 60 days unless the physician decides that this frequency is unnecessary and records the reasons for that decision.

Subpart G—Standards for Intermediate Care Facilities for the Mentally Retarded

§ 442.400 Basis and purpose.

This subpart implements section 1905 (c) and (d) of the Act which gives the Secretary authority to prescribe standards for intermediate care facility services in institutions for the mentally retarded or persons with related conditions.

§ 442.401 Definitions.

As used in this subpart:

"Ambulatory" means able to walk without assistance.

"Living unit" means a resident living unit that includes sleeping areas and may include dining and activity areas.

"Mobile nonambulatory" means unable to walk without assistance, but able to move from place to place with the use of a device such as a walker, crutches, a wheel chair, or a wheeled platform.

"Nonambulatory" means unable to walk without assistance.

"Nonmobile" means unable to move from place to place.

"Qualified mental retardation professional" means a person who has specialized training or 1 year of experience in treating or working with the mentally retarded and is one of the following:

(1) A psychologist with a master's degree from an accredited program.

(2) A licensed doctor of medicine or osteopathy.

(3) An educator with a degree in education from an accredited program.

(4) A social worker with a bachelor's degree in—

(i) Social work from an accredited program; or

(ii) A field other than social work and at least 3 years of social work experience under the supervision of a qualified social worker.

(5) A physical or occupational therapist as defined in § 405.1101 (m) or (q) of this chapter.

(6) A speech pathologist or audiologist as defined in § 405.1105(t) of this chapter.

(7) A registered nurse.

(8) A therapeutic recreation specialist who—

(i) Is a graduate of an accredited program; and

(ii) If the State has a licensing or registration procedure, is licensed or registered in the State.

(9) A rehabilitation counselor who is certified by the Committee on Rehabilitation Counselor Certification.

"Resident living" means pertaining to residential services provided by an ICF/MR.

"Training and habilitation services" means those intended to aid the intellectual, sensorimotor, and emotional development of a resident.

ADMINISTRATIVE POLICIES AND PROCEDURES

§ 442.402 Philosophy, objectives, and goals.

(a) The ICF/MR must have a written outline of the philosophy, objectives, and goals it is striving to achieve that includes, at least—

(1) The ICF/MR's role in the State comprehensive program for the mentally retarded;

(2) The ICF/MR's goals for its residents; and

(3) The ICF/MR's concept of its relationship to the parents or legal guardians of its residents.

(b) The outline must be available for distribution to staff, consumer representatives, and the interested public.

§ 442.403 Resident's civil rights.

The ICF/MR must have written policies and procedures that insure the civil rights of all residents.

§ 442.404 Residents' bill of rights.

The ICF/MR must have written policies and procedures that insure the following rights for each resident:

(a) *Information.* (1) Each resident must be fully informed, before or at admission, of his rights and responsibilities and of all rules governing resident conduct.

(2) If the ICF/MR amends its policies on residents' rights and responsibilities and its rules governing conduct, each resident in the ICF/MR at that time must be informed.

(3) Each resident must acknowledge in writing receipt of the information and any amendments to it. A mentally retarded resident's written acknowledgement must be witnessed by a third person.

(4) Each resident must be fully informed in writing of all services available in the ICF/MR and of the charges for these services including any charges for services not paid for by medicaid or not included in the ICF/MR's basic rate per day. The ICF/MR must provide this information either before or at the time of admission and on a continuing basis as changes occur in services or charges during the resident's stay.

(b) *Medical condition and treatment.* (1) Each resident must—

(i) Be fully informed by a physician of his health and medical condition unless the physician decides that informing the resident is medically contraindicated;

(ii) Be given the opportunity to participate in planning his total care and medical treatment;

(iii) Be given the opportunity to refuse treatment; and

(iv) Give informed, written consent before participating in experimental research.

(2) If the physician decides that informing the resident of his health and medical condition is medically contraindicated, he must document this decision in the resident's record.

(c) *Transfer and discharge.* Each resident must be transferred or discharged only for—

(1) Medical reasons;

(2) His welfare or that of the other residents; or

(3) Nonpayment except as prohibited by the medicaid program.

(d) *Exercising rights.* Each resident must be—

(1) Encouraged and assisted to exercise his rights as a resident of the ICF/MR and as a citizen; and

(2) Allowed to submit complaints or recommendations concerning the policies and services of the ICF/MR to staff or to outside representatives of the resident's choice or both, free from restraint, interference, coercion, discrimination, or reprisal.

(e) *Financial affairs.* Each resident must be allowed to manage his personal financial affairs. If a resident requests assistance from the ICF/MR in managing his personal financial affairs—

(1) The request must be in writing; and

(2) The ICF/MR must comply with the recordkeeping requirements of § 442.406 (d), (e).

(f) *Freedom from abuse and restraints.* (1) Each resident must be free from mental and physical abuse.

(2) Each resident must be free from chemical and physical restraints unless the restraints are—

(i) Authorized by a physician in writing for a specified period of time;

(ii) Used in an emergency under the following conditions:

(A) The use is necessary to protect the resident from injuring himself or others.

(B) The use is authorized by a professional staff member identified in the written policies and procedures of the facility as having authority to do so.

(C) The use is reported promptly to the resident's physician by that staff member; or

(iii) Used during a behavior modification session for a mentally retarded resident under the following conditions:

(A) The use is authorized in writing by a physician or a qualified mental retardation professional.

(B) The parent or legal guardian of the mentally retarded resident gives his informed consent to the use of restraints or aversive stimuli.

(g) *Privacy.* (1) Each resident must be treated with consideration, respect, and full recognition of his dignity and individuality.

(2) Each resident must be given privacy during treatment and care of personal needs.

(3) Each resident's records, including information in an automatic data bank, must be treated confidentially.

(4) Each resident must give written consent before the ICF/MR may release information from his record to someone not otherwise authorized by law to receive it.

(5) A married resident must be given privacy during visits by his spouse.

(6) If both husband and wife are residents of the ICF/MR, they must be permitted to share a room.

(h) *Work.* No resident may be required to perform services for the ICF/MR.

(i) *Freedom of association and correspondence.* Each resident must be allowed to—

(1) Communicate, associate, and meet privately with individuals of his choice, unless this infringes on the rights of another resident; and

(2) Send and receive personal mail unopened.

(j) *Activities.* Each resident must be allowed to participate in social, religious, and community group activities unless a qualified mental retardation professional—

(1) Determines that these activities are contraindicated for a mentally retarded resident; and

(2) Documents that determination in the resident's record.

(k) *Personal possessions.* Each resident must be allowed to retain and use his personal possessions and clothing as space permits.

§ 442.405 Delegation of rights and responsibilities.

(a) The ICF/MR must have written policies and procedures that provide that all rights and responsibilities of a resident pass to the resident's guardian, next of kin, or sponsoring agency or agencies if the resident—

(1) Is adjudicated incompetent under State law; or

(2) Is determined by a qualified mental retardation professional to be incapable of understanding his rights and responsibilities.

(b) If the resident is determined to be incapable of understanding his rights and responsibilities, the qualified mental retardation professional who made the determination must record the specific reason in the resident's record.

§ 442.406 Resident finances.

(a) The ICF/MR must written policies and procedures that protect the financial interests of each resident.

(b) If large sums accrue to a resident, the policies and procedures must provide for appropriate protection of these funds and for counseling the resident concerning their use.

(c) Each resident must be allowed to possess and use money in normal ways or be learning to do so.

(d) The ICF/MR must maintain a current, written financial record for each resident that includes written receipts for—

(1) All personal possessions and funds received by or deposited with the ICF/MR; and

(2) All disbursements made to or for the resident.

(e) The financial record must be available to the resident and his family.

§ 442.407 Policy and procedure manuals.

The ICF/MR must have manuals that—

(a) Describe the policies and procedures in the major operating units of the ICF/MR;

(b) Are current, relevant, and available; and

(c) Are complied with the units.

§ 442.408 Management audit plan.

The ICF/MR must have a plan for a continuing management audit to insure that the ICF/MR—

(a) Complies with State laws and regulations; and

(b) Effectively implements its policies and procedures.

§ 442.409 Governing body.

(a) The ICF/MR must have a governing body that—

(1) Exercises general direction over the affairs of the ICF/MR;

(2) Establishes policies concerning the operation of the ICF/MR and the welfare of the individuals it serves;

(3) Establishes qualifications for the chief executive officer in the following areas:

(i) Education.

(ii) Experience.

(iii) Personal factors.

(iv) Skills; and

(4) Appoints the chief executive officer.

(b) The governing body may consist of one individual or a group.

§ 442.410 Chief executive officer.

(a) The chief executive officer must—

(1) Act for the governing body in the overall management of the ICF/MR; and

(2) Arrange for one individual to be responsible for the administrative direction of the ICF/MR at all times.

(b) The chief executive officer must be an individual licensed in the State as a nursing home administrator or a qualified mental retardation professional except—

If the ICF/MR is licensed as a nursing home, the chief executive officer must be an individual licensed in the State as a nursing home administrator;

(2) If the ICF/MR is a hospital qualifying as an institution for the mentally retarded or persons with related conditions, the chief executive officer must be a hospital administrator.

(c) Job titles for the chief executive officer may include any of the following: superintendent, director, and administrator.

§ 442.411 Qualified mental retardation professional.

The ICF/MR must have a qualified mental retardation professional who is responsible for—

(a) Supervising the delivery of each resident's individual plan of care;

(b) Supervising the delivery of training and habilitation services;

(c) Integrating the various aspects of the ICF/MR's program;

(d) Recording each resident's progress; and

(e) Initiating a periodic review of each individual plan of care for necessary changes.

§ 442.412 Organization chart.

The ICF/MR must have an organization chart that shows—

(a) The major operating programs of the ICF/MR;

(b) The staff divisions of the ICF/MR;

(c) The administrative personnel in charge of the programs and divisions; and

(d) The lines of authority, responsibility, and communication for administrative personnel.

§ 442.413 Staff-resident communications.

The ICF/MR must provide for effective staff and resident participation and communication in the following manners:

(a) The ICF/MR must establish appropriate standing committees such as human rights, research review, and infection.

(b) The committees must meet regularly and include direct-care staff whenever appropriate.

(c) Reports of staff meetings and standing and ad hoc committee meetings must include recommendations and their implementation, and be filed.

§ 442.414 Communication with residents and parents.

(a) The ICF/MR must have an active program of communication with the residents and their families, that includes—

(1) Keeping residents' families or legal guardians informed of resident activities that may be of interest to them or of significant changes in the resident's condition;

(2) Answering communications from resident's relatives promptly and appropriately;

(3) Allowing close relatives and guardians to visit at any reasonable hour, without prior notice, unless the resident's needs limit visits;

(4) Allowing parents to visit any part of the ICF/MR that provides services to residents;

(5) Encouraging frequent and informal visits home by the residents; and

(6) Having rules that make it easy to arrange visits home.

(b) The ICF/MR must insure that individuals allowed to visit the ICF/MR under paragraph (a)(3) of this section do no infringe on the privacy and rights of the other residents.

§ 442.415 Health and safety laws.

The ICF/MR must meet all Federal, State, and local laws, regulations and codes pertaining to health and safety, such as provisions regulating—

(a) Buying, dispensing, safeguarding, administering, and disposing of medications and controlled substances;

(b) Construction, maintenance, and equipment for the ICF/MR;

(c) Sanitation;

(d) Communicable and reportable diseases; and

(e) Post-mortem procedures.

§ 442.416 Research statement.

If the ICF/MR conducts research, it must comply with the statement of assurance on research involving human subjects required by 45 CFR 46.104 through 46.108.

§ 442.417 Agreements with outside resources.

(a) If the ICF/MR does not employ a qualified professional to furnish a required institutional service, it must have in effect a written agreement with a qualified professional outside the ICF/MR to furnish the required service.

(b) The agreement must—

(1) Contain the responsibilities, functions, objectives, and other terms agreed to by the ICF/MR and the qualified professional; and

(2) Be signed by the administrator or his representative and by the qualified professional.

ADMISSION AND RELEASE

§ 442.418 Admission criteria and evaluations.

(a) Except as provided in paragraph (c) of this section, an ICF/MR may not admit an individual as a resident unless his needs can be met and an interdisciplinary professional team has determined that admission is the best available plan for that individual.

(b) The team must—

(1) Conduct a comprehensive evaluation of the individual covering physical, emotional, social, and cognitive factors; and

(2) Before the individual's admission—

(i) Define his need for service without regard to the availability of those services; and

(ii) Review all available and applicable programs of care, treatment, and training and record its findings.

(c) If admission is not the best plan but the individual must be admitted nevertheless, the ICF/MR must—

(1) Clearly acknowledge that the admission is inappropriate; and

(2) Initiate plans to actively explore alternatives.

§ 442.419 Availability of rules and procedures.

The facility must make available for distribution a summary of the laws, regulations, and procedures concerning admission, readmission, and release of a resident.

§ 442.420 Number of residents.

The ICF/MR must admit only that number of individuals that does not exceed—

(a) Its rated capacity; and

(b) Its capability to provide adequate programing.

§ 442.421 Review of preadmission evaluation.

Within 1 month after admission, the interdisciplinary professional team must—

(a) Review and update the preadmission evaluation with the participation of direct care personnel;

(b) Develop, with the participation of direct care personnel, a prognosis that can be used for programing and placement;

(c) Record the results of the evaluation in the resident's record kept in the living unit; and

(d) Write an interpretation of the evaluation in terms of specific actions to be taken for—

(1) The direct care personnel and the special services staff responsible for carrying out the resident's program; and

(2) The resident's parents or legal guardian.

§ 442.422 Annual review of resident's status.

(a) All relevant personnel of the ICF/MR, including personnel in the living unit, must jointly review the status of each resident at least once a year and produce program recommendations.

(b) This review must include consideration of the following:

(1) The advisability of continued residence and alternative programs.

(2) When the resident legally becomes an adult—

(i) The need for guardianship; and

(ii) How the resident may exercise his civil and legal rights.

§ 442.423 Record and reports of reviews.

The results of the reviews required by §§ 442.421 and 442.422 must be—

(a) Recorded in the resident's record kept in the living unit;

(b) Made available to personnel involved in the direct care of the resident;

(c) Interpreted to the resident's parents or legal guardian who are involved in planning and decisionmaking; and

(d) Interpreted to the resident, when appropriate.

§ 442.424 Release from the ICF/MR.

(a) The ICF/MR must establish procedures for counseling a parent or guardian who requests the release of a resident concerning the advantages and disadvantages of the release.

(b) Planning for release of a resident must include providing for appropriate services in the resident's new environment, including protective supervision and other followup services.

(c) When a resident is permanently released, the ICF/MR must prepare and place in the resident's record a summary of findings, progress, and plans.

§ 442.425 Transfer to another facility.

(a) Except as provided in paragraph (b) of this section, the ICF/MR must have in effect a transfer agreement with one or more hospitals sufficiently close by to make feasible the prompt transfer of the resident and his records to the hospital and to support a working arrangement between the ICF/MR and the hospital for providing inpatient hospital services to residents when needed.

(b) If the survey agency finds that the ICF/MR tried in good faith to enter into an agreement but could not, the ICF/MR will be considered to meet the requirements of paragraph (a) as long as the survey agency finds that it is in the public interest and essential to assuring ICF/MR services for eligible individuals in the community.

(c) When a resident is transferred to another facility, the ICF/MR making the transfer must—

(1) Record the reason for the transfer and a summary of findings, progress, and plans; and

(2) Except in an emergency, inform the resident and his parent or guardian in advance and obtain their written consent to the transfer.

§ 442.426 Emergencies or death of a resident.

(a) The ICF/MR must notify promptly the resident's next of kin or guardian of any unusual occurence concerning the resident, including serious illness, accident, or death.

(b) If any autopsy is performed after a resident's death—

(1) A qualified physician who has no conflict of interest or loyalty to the ICF/MR must perform the autopsy; and

(2) The resident' family must be told of the autopsy findings if they so desire.

PERSONNEL POLICIES

§ 442.427 Written policies.

The ICF/MR must—

(a) Have written personnel policies that are available to all employees;

(b) Make written job descriptions available for all positions; and

(c) Have written poljcies that prohibit employees with symptoms or signs of a communicable disease from working.

§ 442.428 Licensure and professional standards.

The ICF/MR must—

(a) Require the same licensure, certification, or standards for positions in the facility as are required for compa-

rable positions in community practice; and

(b) Take into account in its personnel activities the ethical standards of professional conduct developed by professional societies.

§ 442.429. Suspension and dismissal.

The ICF/MR must have an authorized procedure, consistent with due process, for suspending or dismissing an employee.

§ 442.430 Staff treatment of residents.

(a) The ICF/MR must have written policies that prohibit mistreatment, neglect, or abuse of a resident by an employee of the ICF/MR.

(b) The ICF/MR must insure that all alleged violations of these policies are reported immediately.

(c) The ICF/MR must have evidence that—

(1) All violations are investigated thoroughly;

(2) The results of the investigation are reported to the chief executive or his designated representative within 24 hours of the report of the incident; and

(3) If the alleged violation is verified, the chief executive officer imposes an appropriate penalty.

§ 442.431 Sufficient staffing and resident work.

(a) The ICF/MR must have a staff of sufficient size that the ICF/MR does not depend on residents or volunteers for services.

(b) The ICF/MR must have a written policy to protect residents from exploitation if they engage in productive work.

§ 442.432 Staff training program.

(a) The ICF/MR must have a staff training program, appropriate to the size and nature of the ICF/MR, that includes—

(1) Orientation for each new employee to acquaint him with the philosophy, organization, program, practices, and goals of the ICF/MR;

(2) Inservice training for any employee who has not achieved the desired level of competence;

(3) Continuing inservice training for all employees to update and improve their skills; and

(4) Supervisory and management training for each employee who is in, or a candidate for, a supervisory position.

(b) If appropriate to the size and nature of the ICF/MR it must have someone designated to be responsible for staff development and training.

RESIDENT LIVING

§ 442.433 Responsibilities of living unit staff.

(a) The living unit staff must make care and development of the residents their primary responsibility. This includes training each resident in the activities of daily living and in the development of self-help and social skills.

(b) The ICF/MR must insure that the staff are not diverted from their primary responsibilities by excessive housekeeping or clerical duties or other activities not related to resident care.

(c) Members of the living unit staff from all shifts must participate in appropriate activities relating to the care and development of the resident including, at least, referral, planning, initiation, coordination, implementation, followthrough, monitoring, and evaluation.

§ 442.434 Resident evaluation and program plans.

The ICF/MR must have specific evaluation and program plans for each resident that are—

(a) Available to direct care staff in each living unit; and

(b) Reviewed by a member or members of an interdisciplinary professional team at least monthly with documentation of the review entered in the resident's record.

§ 442.435 Resident activities.

(a) The ICF/MR must develop an activity schedule for each resident that—

(1) Does not allow periods of unscheduled activity to extend longer than 3 continuous hours;

(2) Allows free time for individual or group activities using appropriate materials, as specified by the program team; and

(3) Includes planned outdoor periods all year round.

(b) Each resident's activity schedule must be available to direct care staff and be carried out daily.

(c) The ICF/MR must insure that a multiple-handicapped or nonambulatory resident—

(1) Spends a major portion of the waking day out of bed;

(2) Spends a portion of the waking day out of his bedroom area;

(3) Has planned daily activity and exercise periods; and

(4) Moves around by various methods and devices whenever possible.

§ 442.436 Personal possessions.

The ICF/MR must allow the residents to have personal possessions such as toys, books, pictures, games, radios, arts and crafts materials, religious articles, toiletries, jewelry, and letters.

§ 442.437 Control and discipline of residents.

(a) The ICF/MR must have written policies and procedures for the control and discipline of residents that are available in each living unit and to parents and guardians.

(b) If appropriate, residents must participate in formulating these policies and procedures.

(c) The ICF/MR may not allow—

(1) Corporal punishment of a resident;

(2) A resident to discipline another resident, unless it is done as part of an organized self-government program conducted in accordance with written policy; or

(3) A resident to be placed alone in a locked room.

§ 442.438 Physical restraint of residents.

(a) Except as provided for behavior modification programs in § 442.422, the ICF/MR may allow the use of physical restraint on a resident only if absolutely necessary to protect the resident from injuring himself or others.

(b) The ICF/MR may not use physical restraint—

(1) As punishment;

(2) For the convenience of the staff; or

(3) As a substitute for activities or treatment.

(c) The ICF/MR must have a written policy that specifies—

(1) How and when physical restraint may be used;

(2) The staff members who must authorize its use; and

(3) The method for monitoring and controlling its use.

(d) An order for physical restraint may not be in effect longer than 12 hours.

(e) Appropriately trained staff must check a resident placed in a physical restraint at least every 30 minutes and keep a record of these checks.

(f) A resident who is in a physical restraint must be given an opportunity for motion and exercise for a period of not less than 10 minutes during each 2 hours of restraint.

§ 442.439 Mechanical devices used for physical restraint.

(a) Mechanical devices used for physical restraint must be designed and used in a way that causes the resident no physical injury and the least possible physical discomfort.

(b) A totally enclosed crib or a barred enclosure is a physical restraint.

(c) Mechanical supports used to achieve proper body position and balance are not physical restraints. However, mechanical supports must be designed and applied—

(1) Under the supervision of a qualified professional; and

(2) In accordance with principles of good body alinement, concern for circulation, and allowance for change of position.

§ 442.440 Chemical restraint of residents.

The ICF/MR may not use chemical restraint—

(a) Excessively;

(b) As punishment;

(c) For the convenience of the staff;

(d) As a substitute for activities or treatment; or

(e) In quantities that interfere with a resident's habilitation program.

§ 442.441 Behavior modification programs.

(a) For purposes of this section—

"Aversive stimuli" means things or events that the resident finds unpleasant or painful that are used to immediately discourage undesired behavior.

"Time out" means a procedure designed to improve a resident's behavior by removing positive reinforcement when his behavior is undesirable.

(b) Behavior modification programs involving the use of aversive stimuli or time-out devices must be—

(1) Reviewed and approved by the ICF/MR's human rights committee or the qualified mental retardation professional;

(2) Conducted only with the consent of the affected resident's parents or legal guardian; and

(3) Described in written plans that are kept on file in the ICF/MR.

(c) A physical restraint used as a time-out device may be applied only during behavior modification exercises and only in the presence of the trainer.

(d) For time-out purposes, time-out devices and aversive stimuli may not be used for longer than one hour, and then only during the behavior modification program and only under the supervision of the trainer.

§ 442.442 Resident clothing.

The ICF/MR must insure that each resident—

(a) Has enough neat, clean, suitable, and seasonable clothing;

(b) Has his own clothing marked with his name when necessary;

(c) Is dressed daily in his own clothes unless this is contraindicated in written medical orders;

(d) Is trained and encouraged, as appropriate, to—

(1) Select his daily clothing;

(2) Dress himself;

(3) Change his clothes to suit his activities; and

(e) Has storage space for his clothing that is accessible to him even if he is in a wheelchair.

§ 442.443 Health, hygiene, grooming and toilet training.

(a) Each resident must be trained to be as independent as possible in health, hygiene, and grooming practices, including bathing, brushing teeth, shampooing, combing and brushing hair, shaving, and caring for toenails and fingernails.

(b) Each resident who does not eliminate appropriately and independently must be in a regular, systematic toilet training program and a record must be kept of his progress in the program.

(c) A resident who is incontinent must be bathed or cleaned immediately upon voiding or soiling, unless specifically contraindicated by the training program, and all soiled items must be changed.

(d) The ICF/MR must establish procedures for—

(1) Weighing each resident monthly, unless the special needs of the resident require more frequent weighing;

(2) Measuring the height of each resident every 3 months until the resident reaches the age of maximum growth;

(3) Maintaining weight and height records for each resident; and

(4) Insuring that each resident maintains a normal weight.

(e) At least every 3 days, a physician must review orders prescribing bed rest or prohibiting a resident from being outdoors.

(f) The ICF/MR must furnish, maintain in good repair, and encourage the use of dentures, eyeglasses, hearing aids, braces, and other aids prescribed for a resident by an appropriate specialist.

§ 442.444 Grouping and organization of living units.

(a) The ICF/MR may not house residents of grossly different ages, developmental levels, and social needs in close physical or social proximity unless the housing is planned to promote the growth and development of all those housed together.

(b) The ICF/MR may not segregate residents on the basis of their physical handicaps: It must integrate residents who are mobile nonambulatory, deaf, blind, epileptic, and so forth with others of comparable social and intellectual development.

§ 442.445 Resident living staff.

(a) Each resident living unit must have sufficient, appropriately qualified, and adequately trained personnel to conduct the resident living program as required by this subpart.

(b) The ICF/MR must have an individual, whose training and experience is appropriate to the program, who is administratively responsible for resident living personnel.

(c) Each resident living unit, regardless of organization or design, must have, as a minimum, overall staff-resident ratios (allowing for a 5-day work week plus holiday, vacation, and sick time) as follows unless program needs justify otherwise:

(1) For units serving children under the age of 6 years, severely and profoundly retarded, severely physically handicapped, or residents who are aggressive, assaultive, or security risks, or who manifest severely hyperactive or psychotic-like behavior, the overall ration is 1 to 2.

(2) For units serving moderately retarded residents requiring habit training, the overall ration is 1 to 2.5.

(3) For units serving residents in vocational training programs and adults who work in sheltered employment situations, the overall ration is 1 to 5.

§ 442.446 Resident living areas.

The ICF/MR must design and equip the resident living areas for the comfort and privacy of each resident.

§ 442.447 Resident bedrooms: Space and occupancy.

(a) Bedrooms must—

(1) Be at or above street grade level;

(2) Be outside rooms;

(3) Be equipped with or located near adequate toilet and bathing facilities;

(4) Accommodate no more than 4 residents unless granted a variance under paragraph (b) of this section; and

(5) Measure at least 60 square feet per resident in multiple resident bedrooms and at least 80 square feet in single resident bedrooms.

(b) The survey agency may grant a variance from the limit of 4 residents per room if it finds that—

(1) A physician or psychologist who meets the definition of a qualified mental retardation professional in § 442.401 has justified in each affected resident's plan of care that assignment to a bedroom of more than 4 residents is in accordance with the program needs of that resident; and

(2) The variance does not adversely affect the health or safety of the residents.

(c) The variance may be granted only for the period of a specific certification.

§ 442.448 Resident bedrooms: Furniture and bedding.

The ICF/MR must provide each resident with—

(a) A separate bed of proper size and height for the convenience of the resident;

(b) A clean, comfortable mattress;

(c) Bedding appropriate to the weather and climate; and

(d) Appropriate furniture, such as a chest of drawers, a table or desk, and

an individual closet with clothes racks and shelves accessible to the resident.

§ 442.449 Storage space in living units.

The ICF/MR must provide—

(a) Space for equipment for daily out-of-bed activity for all residents who are not yet mobile, except those who have a short-term illness or those few residents for whom out-of-bed activity is a threat to life;

(b) Suitable storage space, accessible to the resident, for personal possessions, such as toys and prosthetic equipment; and

(c) Adequate clean linen and dirty linen storage areas for each living unit.

§ 442.450 Resident bathrooms.

(a) The ICF/MR must—

(1) Have toilet and bathing facilities appropriate in number, size, and design to meet the needs of the residents;

(2) Provide for individual privacy in toilets, bathtubs, and showers unless specifically contraindicated by program needs;

(3) Equip bathrooms and bathroom appliances for use by the physically handicapped; and

(4) Control the temperature of the hot water at all taps to which residents have access, by using thermostatically controlled mixing valves or other means, so that the water does not exceed 110 degrees fahrenheit.

(b) The survey agency may grant a variance from the requirement in paragraph (a)(4) of this section if—

(1) The hot water taps are in supervised areas; and

(2) The purpose of the variance is to train residents in the use of hot water.

(c) The variance must be part of the survey record.

§ 442.451 Heating and ventilation in living units.

(a) Each habitable room in the ICF/MR must have—

(1) At least one window; and

(2) Direct outside ventilation by means of windows, louvers, air conditioning, or mechanical ventilation horizontally and vertically.

(b) The ICF/MR must—

(1) Maintain the temperature and humidity within a normal comfort range by heating, air conditioning or other means; and

(2) Use a heating apparatus that does not constitute a burn hazard to residents.

§ 442.452 Floors in living units.

The ICF/MR must have—

(a) Floors that have a resilient, nonabrasive, and slip-resistant surface; and

(b) Nonabrasive carpeting, if the living unit is carpeted and serves residents who crawl.

§ 442.453 Emergency lighting.

If a living unit houses more than 15 residents, it must have emergency lighting with automatic switches for stairs and exits.

PROFESSIONAL AND SPECIAL PROGRAMS AND SERVICES

§ 442.454 Needed services.

In addition to the resident living services detailed in §§ 442.432 through 442.453, the ICF/MR must provide professional and special programs and services to residents based upon their needs for these programs and services.

§ 442.455 Quality standards for outside resources.

(a) Programs and services provided by the ICF/MR or to the ICF/MR by outside agencies or individuals must meet the standards for quality of services required in this subpart.

(b) All contracts for these services must state that these standards will be met.

§ 442.456 Planning and evaluation.

Interdisciplinary teams consisting of individuals representative of the professions or service areas included in this subpart that are relevant in each particular case, must—

(a) Evaluate each resident's needs;

(b) Plan an individualized habilitation program to meet each resident's identified needs; and

(c) Periodically review each resident's responses to his program and revise the program accordingly.

DENTAL SERVICES

§ 442.457 Diagnostic services.

(a) The ICF/MR must provide each resident with comprehensive diagnostic dental services that include a complete extraoral and intraoral examination, using all diagnostic aids necessary to properly evaluate the resident's oral condition, not later than 1 month after a resident's admission to the ICF/MR unless he received the examination within 6 months before admission.

(b) The ICF/MR must review the results of the examination and enter them in the resident's record.

§ 442.458 Treatment.

The ICF/MR must provide each resident with comprehensive dental treatment that includes—

(a) Provision for emergency dental treatment on a 24-hour-a-day basis by a qualified dentist; and

(b) A system that assures that each resident is reexamined as needed but at least once a year.

§ 442.459 Education and training.

The ICF/MR must provide education and training in the maintenance of oral health that includes—

(a) A dental hygiene program that informs residents and all staff on nutrition and diet control measures and residents and living unit staff on proper oral hygiene methods; and

(b) Instruction of parents or guardians in the maintenance of proper oral hygiene in appropriate instances, for example when a resident leaves the ICF/MR.

§ 442.460 Records.

The ICF/MR must—

(a) Keep a permanent dental record for each resident;

(b) Enter a summary dental progress report at stated intervals in each resident's record kept in the living unit;

(c) Provide a copy of the permanent dental record to any facility to which the resident is transferred.

§ 442.461 Formal arrangements.

The ICF/MR must have a formal arrangement for providing each resident with the dental services required under this subpart.

§ 442.462 Staff.

(a) The ICF/MR must have enough qualified dental personnel and support staff to carry out the dental services program.

(b) Each dentist and dental hygienist providing services to the facility must be licensed to practice in the State.

TRAINING AND HABILITATION SERVICES

§ 442.463 Required services.

(a) The ICF/MR must provide training and habilitation services to all residents, regardless of age, degree of retardation, or accompanying disabilities or handicaps.

(b) Individual evaluations of residents must—

(1) Be based upon the use of empirically reliable and valid instruments, whenever these instruments are available; and

(2) Provide the basis for prescribing an appropriate program of training experiences for the resident.

(c) The ICF/MR must have written training and habilitation objectives for each resident that are—

(1) Based upon complete and relevant diagnostic and prognostic data; and

(2) Stated in specific behavioral terms that permit the progress of each resident to be assessed.

(d) The ICF/MR must provide evidence of services designed to meet the training and habilitation objectives for each resident.

(e) The training and habilitation staff must—

(1) Maintain a functional training and habilitation record for each resident; and

(2) Provide training and habilitation services to residents with hearing, vision, perceptual, or motor impairments.

§ 442.464 Staff.

The ICF/MR must have enough qualified training and habilitation personnel and support staff, supervised by a qualified mental retardation professional, to carry out the training and habilitation program.

FOOD AND NUTRITION SERVICES

§ 442.465 Required services.

The ICF/MR's food services must include—

(a) Menu planning;

(b) Initiating food orders or requisitions;

(c) Establishing specifications for food purchases and insuring that the specifications are met;

(d) Storing and handling food;

(e) Preparing and serving food;

(f) Maintaining sanitary standards in compliance with State and local regulations; and

(g) Orienting, training, and supervising food service personnel.

§ 442.466 Diet requirements.

(a) The ICF/MR must provide each resident with a nourishing, well-balanced diet.

(b) Modified diets must be—

(1) Prescribed by the resident's interdisciplinary team with a record of the prescription kept on file;

(2) Planned, prepared, and served by individuals who have received adequate instruction; and

(3) Periodically reviewed and adjusted as needed.

(c) The ICF/MR must furnish a nourishing, well-balanced diet, in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, adjusted for age, sex, activity, and disability, unless otherwise required by medical needs. (Recommended Dietary Allowances (8th ed., 1974) is available from the Printing and Publication Office, National Academy of Sciences, Washington, D.C. 20418.)

(d) A resident may not be denied a nutritionally adequate diet as a form of punishment.

§ 442.467 Meal service.

(a) The ICF/MR must serve at least three meals daily, at regular times comparable to normal mealtimes in the community with—

(1) Not more than 14 hours between a substantial evening meal and breakfast of the following day; and

(2) Not less than 10 hours between breakfast and the evening meal of the same day.

(b) Food must be served—

(1) In appropriate quantity;

(2) At appropriate temperature;

(3) In a form consistent with the developmental level of the resident; and

(4) With appropriate utensils.

(c) Food served and uneaten must be discarded.

§ 442.468 Menus.

(a) Menus must—

(1) Be written in advance;

(2) Provide a variety of foods at each meal; and

(3) Be different for the same days of each week and adjusted for seasonal changes.

(b) The ICF/MR must keep on file, for at least 30 days, records of menus as served and of food purchased.

§ 442.469 Food storage.

The ICF/MR must store—

(a) Dry or staple food items at least 12 inches above the floor, in a ventilated room not subject to sewage or waste water backflow or contamination by condensation, leakage, rodents or vermin; and

(b) Perishable foods at proper temperatures to conserve nutritive values.

§ 442.470 Work areas.

The ICF/MR must—

(a) Have effective procedures for cleaning all equipment and work areas; and

(b) Provide handwashing facilities, including hot and cold water, soap, and paper towels adjacent to work areas.

§ 442.471 Dining areas and service.

The ICF/MR must—

(a) Serve meals for all residents, including the mobile nonambulatory, in dining rooms, unless otherwise required for health reasons or by decision of the team responsible for the resident's program;

(b) Provide table service for all residents who can and will eat at a table, including residents in wheelchairs;

(c) Equip areas with table, chairs, eating utensils, and dishes designed to meet the developmental needs of each resident; and

(d) Supervise and staff dining rooms adequately to direct self-help dining procedures and to assure that each resident receives enough food.

§ 442.472 Training of residents and direct-care staff.

(a) The ICF/MR must provide residents with systematic training to develop appropriate eating skills, using special eating equipment and utensils if it serves the developmental process.

(b) Direct-care staff must be trained in and use proper feeding techniques.

(c) The ICF/MR must insure that residents eat in an upright position, unless medically contraindicated, and in a manner consistent with their developmental needs.

§ 442.473 Staff.

(a) The ICF/MR must have enough competent personnel to meet the food and nutrition needs of residents.

(b) A dietitian who directs food and nutrition services in ICF's/MR of 20 beds or more must meet the qualification requirements of § 405.1101 of this chapter.

(c) The ICF/MR must designate a staff member who is trained or experienced in food management or nutrition to direct food and nutrition services in an ICF/MR with less than 20 beds.

MEDICAL SERVICES

§ 442.474 Required services.

The ICF/MR must—

(a) Provide medical services through direct contact between physicians and residents and through contact between physicians and individuals working with the residents;

(b) Provide health services including treatment, medications, diet, and any other health service prescribed or planned for the resident, 24 hours a day;

(c) Have available electroencephalographic services as needed;

(d) Have enough space, facilities, and equipment to fulfill the medical needs of residents; and

(e) Provide evidence, such as utilization review committee records, that hospital and laboratory services are used in accordance with professional standards.

§ 442.475 Goals and evaluations.

(a) Physicians must participate, when appropriate, in—

(1) The continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs; and

(2) The development for each resident of a detailed, written statement of—

(i) Case management goals for physical and mental health, education, and functional and social competence; and

(ii) A management plan detailing the various habilitation or rehabilitation services to achieve those goals, with

clear designation of responsibility for implementation.

(b) The ICF/MR must review and update the statement of treatment goals and management plans as needed, but at least annually, to insure—

(1) Continuing appropriateness of the goals;

(2) Consistency of management methods with the goals; and

(3) The achievement of progress toward the goals.

§ 442.476 Arrangements with outside resources.

The ICF/MR must—

(a) Have a formal arrangement for providing each resident with medical care that includes care for medical emergencies on a 24-hour-a-day basis;

(b) Designate a physician, licensed to practice medicine in the State, to be responsible for maintaining the general health conditions and practices of the ICF/MR and

(c) Maintain effective arrangements, for residents to receive prompt medical and remedial services that they require but that the ICF/MR does not regularly provide.

§ 442.477 Preventive health services.

The ICF/MR must have preventive health services for residents that include—

(a) Means for the prompt detection and referral of health problems, through adequate medical surveillance, periodic inspection, and regular medical examinations;

(b) Annual physical examinations that include—

(1) Examination of vision and hearing; and

(2) Routine screening laboratory examinations as determined necessary by the physician, and special studies when needed;

(c) Immunizations, using as a guide the recommendations of the Public Health Service Advisory Committee on Immunization Practices and of the Committee on the Control of Infectious Diseases of the American Academy of Pedeatrics;

(d) Tuberculosis control, appropriate to the ICF/MR's population, in accordance with the recommendations of the American College of Chest Physicians or the section on diseases of the chest of the American Academy of Pediatrics or both; and

(e) Reporting of communicable diseases and infections in accordance with law.

§ 442.478 Required services.

The ICF/MR must provide residents with nursing services, in accordance with their needs, that include, as appropriate, the following:

(a) Registered nurse participation in—

(1) The preadmission evaluation study and plan;

(2) The evaluation study, program design, and placement of the resident at the time of admission;

(3) The periodic reevaluation of the type, extent, and quality of services and programing;

(4) The development of the discharge plan; and

(5) The referral to appropriate community resources.

(b) Training in habits of personal hygiene, family life, and sex education that includes but is not limited to family planning and venereal disease counseling.

(c) Control of communicable diseases and infections through—

(1) Identification and assessment;

(2) Reporting to medical authorities; and

(3) Implementation of appropriate protective and preventive measures.

(4) Development of a written nursing services plan for each resident as part of the total habilitation program.

(5) Modification of the nursing plan, in terms of the resident's daily needs, at least annually for adults and more frequently for children, in accordance with developmental changes.

§ 442.479 Training.

(a) A registered nurse must participate, as appropriate, in the planning and implementation of training of the ICF/MR's personnel.

(b) The ICF/MR must have direct-care personnel trained in—

(1) Detecting signs of illness or dysfunction that warrant medical or nursing intervention;

(2) Basic skills required to meet the health needs and problems of the residents; and

(3) First aid for accident or illness.

§ 442.480 Staff.

(a) The ICF/MR must have available enough nursing staff, which may include currently licensed practical nurses and other supporting personnel, to carry out the various nursing services.

(b) The individual responsible for the delivery of nursing services must have knowledge and experience in the field of developmental disabilities.

(c) Nursing service personnel at all levels of experience and competence must be—

(1) Assigned responsibilities in accordance with their qualifications;

(2) Delegated authority commensurate with their responsibility; and

(3) Provided appropriate professional nursing supervision.

§ 442.481 Supervision of health services.

(a) The ICF/MR must have a registered nurse or licensed practical or vocational nurse to supervise the health services full time, 7 days a week, on the day shift.

(b) The nurse must have a current license to practice in the State.

(c) If the ICF/MR employs a licensed practical or vocational nurse to supervise health services, it must have a formal arrangement with a registered nurse to consult with the licensed practical or vocational nurse at regular intervals, but not less than 4 hours each week.

(d) To be qualified to serve as a health services supervisor, a licensed practical nurse must—

(1) Be a graduate of a State-approved school of practical nursing;

(2) Have education or other training that the State authority responsible for licensing practical nurses considers equal to graduation from a State-approved school of practical nursing; or

(3) Have passed the Public Health Service examination for waivered licensed practical or vocational nurses.

(e) The ICF/MR may employ as a nurse an individual who is licensed by the State in a category other than registered nurse or licensed practical or vocational nurse if—

(1) The individual has completed a training program to get the license that included at least the same number of classroom and practice hours in all nursing subjects as in the program of a State-approved school of practical or vocational nursing; and

(2) The State agency responsible for licensing the individual submits a report to the Medicaid agency comparing State LPN or vocational nurse course requirements with those for the program completed by the individual.

(f) The ICF/MR must have responsible staff members on duty and awake 24 hours a day to take prompt, appropriate action in case of injury, illness, fire, or other emergency.

(g) An ICF/MR that has 15 beds or less, and only admits residents certified by a physician as not in need of professional nursing services, may meet the requirements of paragraphs (a) through (f) of this section by—

(1) Contracting for the services of a public health nurse or other registered nurse to care for minor illnesses, injuries, or emergencies, and to consult on the health aspects of the individual plan of care; and

(2) Having a responsible staff member on duty 24 hours a day who is immediately accessible to the residents to take reports of injuries, symptoms of illness, and emergencies.

(h) The health services supervisor is responsible for developing, supervising the implementation of, reviewing, and

revising a written health care plan for each resident that is—

(1) Developed and implemented according to the instructions of the attending or staff physician; and

(2) Reviewed and revised as needed but not less often than quarterly.

PHARMACY SERVICES

§ 442.482 Required services.

The ICF/MR must—

(a) Make formal arrangements for qualified pharmacy services, including provision for emergency service.

(b) Have a current pharmacy manual that—

(1) Includes policies and procedures and defines the functions and responsibilities relating to pharmacy services; and

(2) Is revised annually to keep abreast of current developments in services and management techniques; and

(c) Have a formulary system approved by a responsible physician and pharmacist and other appropriate staff. Copies of the ICF/MR's formulary system and of the American Hospital Formulary Service must be located and available in the facility.

§ 442.483 Pharmacist.

(a) Pharmacy services must be provided under the direction of a qualified licensed pharmacists.

(b) The pharmacist must—

(1) When a resident is admitted, obtain, if possible, a history of prescription and nonprescription drugs used and enter this information in the resident's record;

(2) Receive the original, or a direct copy, of the physician's drug treatment order;

(3) Maintain for each resident an individual record of all prescription and nonprescription medications dispensed, including quantities and frequency of refills;

(4) Participate, as appropriate, in the continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs; and

(5) Establish quality specifications for drug purchases and insure that they are met.

(c) A pharmacist or registered nurse must regularly review the medication record of each resident for potential adverse reactions, allergies, interactions, contraindications, rationality and laboratory test modifications and advise the physician of any recommended changes with reasons and with an alternate drug regimen.

(d) As appropriate to the ICF/MR, the responsible pharmacist, physician, nurse, and other professional staff must write policies and procedures that govern the safe administration and handling of all drugs. The following policies and procedures must be included:

(1) There must be a written policy governing the self administration of drugs, whether prescribed or not.

(2) The pharmacist or an individual under his supervision must compound, package, label, and dispense drugs including samples and investigational drugs. Proper controls and records must be kept of these processes.

(3) Each drug must be identified up to the point of administration.

(4) Whenever possible, the pharmacist must dispense drugs that require dosage measurements in a form ready to be administered to the resident.

§ 442.484 Drugs and medications.

(a) A medication must be used only by the resident for whom it is issued. Only appropriately trained staff may administer drugs.

(b) Any drug that is discontinued or outdated and any container with a worn, illegible, or missing label must be returned to the pharmacy for proper disposition.

(c) The ICF/MR must have—

(1) An automatic stop order on all drugs;

(2) A drug recall procedure that can be readily used;

(3) A procedure for reporting adverse drug reactions to the Food and Drug Administration; and

(4) An emergency kit available to each living unit and appropriate to the needs of its residents.

(d) Medication errors and drug reactions must be recorded and reported immediately to the practitioner who ordered the drug.

§ 442.485 Drug storage.

The ICF/MR must—

(a) Store drugs under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security;

(b) Store poisons, drugs used externally, and drugs taken internally on separate shelves or in separate cabinets, at all locations;

(c) Keep medication that is stored in a refrigerator containing other items in a separate compartment with proper security;

(d) Keep all drugs under lock and key unless an authorized individual is in attendance;

(e) If there is a drug storeroom separate from the pharmacy, keep a perpetual inventory of receipts and issues of all drugs from that storeroom; and

(f) Meet the drug security requirements of Federal and State laws that apply to storerooms, pharmacies, and living units.

PHYSICAL AND OCCUPATIONAL THERAPY SERVICES

§ 442.486 Required services.

(a) The ICF/MR must provide physical and occupational therapy services through direct contact between therapists and residents and through contact between therapists and individuals involved with the residents.

(b) Physical and occupational therapy staff must provide treatment training programs that are designed to—

(1) Preserve and improve abilities for independent function, such as range of motion, strength, tolerance, coordination, and activities of daily living; and

(2) Prevent, insofar as possible, irreducible or progressive disabilities through means such as the use of orthotic and prosthetic appliances, assistive and adaptive devices, positioning, behavior adaptations, and sensory stimulation.

(c) The therapist must—

(1) Work closely with the resident's primary physician and with other medical specialists;

(2) Record regularly and evaluate periodically the treatment training progress; and

(3) Use the treatment training progress as the basis for continuation or change in the resident's program.

§ 442.487 Records and evaluations.

The ICF/MR must have evaluation results, treatment objectives, plans and procedures, and continuing observations of treatment progress—

(a) Recorded accurately, summarized, and communicated to all relevant parties;

(b) Used in evaluating progress; and

(c) Included in the resident's record kept in the living unit.

§ 442.488 Staff and facilities.

(a) The ICF/MR must have available enough qualified staff and support personnel to carry out the various physical and occupational therapy services in accordance with stated goals and objectives.

(b) Physical and occupational therapy personnel must be—

(1) Assigned responsibilities in accordance with their qualifications;

(2) Delegated authority commensurate with their responsibilities; and

(3) Provided professional direction and consultation.

(c) Therapy assistants must work under the supervision of a qualified therapist.

(d) Physical and occupational therapists and therapy assistants must meet the qualification requirements of § 405.1101 of this chapter.

(e) The ICF/MR must provide enough space and equipment and sup-

plies for efficient and effective physical and occupational therapy services.

PSYCHOLOGICAL SERVICES

§ 442.489 Required services.

The ICF/MR must—

(a) Provide psychological services through personal contact between psychologists and residents and through contact between psychologists and individuals involved with the residents; and

(b) Have available enough qualified staff and support personnel to furnish the following psychological services based on need:

(1) Psychological services for residents, including evaluation, consultation, therapy, and program development.

(2) Administration and supervision of psychological services.

(3) Staff training.

§ 442.490 Psychologist.

Psychologists must—

(a) Have at least a master's degree from an accredited program and experience or training in the field of mental retardation;

(b) Participate, when appropriate, in the continuing interdisciplinary evaluation of each individual resident, for the purposes of beginning, monitoring, and following up on the resident's individualized habilitation program;

(c) Report and disseminate evaluation results in a manner that—

(1) Promptly provides information useful to staff working directly with the resident; and

(2) Maintains accepted standards of confidentiality;

(d) Participate, when appropriate, in the development of written, detailed, specific, and individualized habilitation program plans that—

(1) Provide for periodic review, followup, and updating; and

(2) Are designed to maximize each resident's development and acquisition of the following: Perceptual skills, sensorimotor skills, self-help skills, communication skills, social skills, self-direction, emotional stability, and effective use of time, including leisure time.

RECREATION SERVICES

§ 442.491 Required services.

The ICF/MR must—

(a) Coordinate recreational services with other services and programs provided to each resident, in order to—

(1) Make the fullest possible use of the ICF/MR's resources; and

(2) Maximize benefits to the residents;

(b) Design and construct or modify recreation areas and facilities so that all residents, regardless of their disabilities, have access to them; and

(c) Provide recreation equipment and supplies in a quantity and variety that is sufficient to carry out the stated objectives of the activities programs.

§ 442.492 Records.

The ICF/MR's resident records must include—

(a) Periodic surveys of the residents' recreation interests; and

(b) The extent and level of the residents' participation in the recreation program.

§ 442.493 Staff.

(a) The ICF/MR must have enough qualified staff and support personnel available to carry out the various recreation services in accordance with stated goals and objectives.

(b) Staff conducting the recreation program must have—

(1) A bachelor's degree in recreation, or in a speciality area, such as art, music, or physical education;

(2) An associate degree in recreation and 1 year of experience in recreation;

(3) A high school diploma, or an equivalency certificate and—

(i) Two years of experience in recreation; or

(ii) One year of experience in recreation plus completion of comprehensive inservice training in recreation; or

(4) Demonstrated proficiency and experience in conducting activities in one or more recreation program areas.

SOCIAL SERVICES

§ 442.494 Required services.

The ICF/MR must provide, as part of an interdisciplinary set of services, social services to each resident directed toward—

(a) Maximizing the social functioning of each resident;

(b) Enhancing the coping capacity of each resident's family;

(c) Asserting and safeguarding the human and civil rights of the retarded and their families; and

(d) Fostering the human dignity and personal worth of each resident.

§ 442.495 Social workers.

(a) During the evaluation process to determine whether or not admission to the ICF/MR is necessary, social workers must help the resident and his family—

(1) Consider alternative services, based on the retarded individual's status and important family and community factors; and

(2) Make a responsible choice as to whether and when residential placement is indicated.

(b) Social workers must participate, when appropriate, in the continuing interdisciplinary evaluation of individual residents for the purposes of beginning, monitoring, and following up on individualized habilitation programs.

(c) During the retarded individual's admission to, and residence in the facility or while he is receiving services from the facility, social workers must, as appropriate, provide liaison between him, the ICF/MR, the family, and the community, in order to—

(1) Help the staff—

(i) Individualize and understand the needs of the resident and his family in relation to each other;

(ii) Understand social factors in the resident's day-to-day behavior, including staff-resident relationships; and

(iii) Prepare the resident for changes in his living situation;

(2) Help the family develop constructive and personally meaningful ways to support the resident's experience in the ICF/MR through—

(i) Counseling concerning the problems of changes in family structure and functioning; and

(ii) referral to specific services, as appropriate; and

(3) Help the family participate in planning for the resident's return to home or other community placement.

(d) After the resident leaves the ICF/MR, social workers must provide systematic followup to assure referral to appropriate community agencies.

(e) The ICF/MR must have available enough qualified staff and support personnel to carry out the various social services activities.

(f) Social workers providing service to the ICF/MR must meet the qualification requirements of § 405.1101 of this chapter.

(g) Social work assistants or aides employed by the ICF/MR must be supervised by a social worker.

SPEECH PATHOLOGY AND AUDIOLOGY SERVICES

§ 442.496 Required services.

(a) The ICF/MR must provide speech pathology and audiology services through direct contact between speech pathologists and audiologists and residents, and working with other personnel, including but not limited to teachers and direct-care staff.

(b) Speech pathology and audiology services available to the ICF/MR must include—

(1) Screening and evaluation of residents with respect to speech and hearing functions;

(2) Comprehensive audiological assessment of residents, as indicated by screening results, that include tests of puretone air and bone conduction, speech audiometry, and other procedures, as necessary, and the assessment of the use of visual cues;

(3) Assessment of the use of amplification;

(4) Provision for procurement, maintenance, and replacement of hearing aids, as specified by a qualified audiologist;

(5) Comprehensive speech and language evaluation of residents, as indicated by screening results, including appraisal of articulation, voice, rhythm, and language;

(6) Participation in the continuing interdisciplinary evaluation of individual residents for purposes of beginning, monitoring, and following up on individualized habilitation programs;

(7) Treatment services as an extension of the evaluation process, that include—

(i) Direct counseling with residents;

(ii) Consultation with appropriate staff for speech improvement and speech education activities; and

(iii) Work with appropriate staff to develop specialized programs for developing each resident's communication skills in comprehension, including speech, reading, auditory training, and hearing aid utilization, and skills in expression, including improvement in articulation, voice, rhythm, and language; and

(8) Participation in inservice training programs for direct-care and other staff.

§ 442.497 Evaluations and assessments.

(a) Speech pathologists and audiologists must accurately and systematically report evaluation and assessment results in order to—

(1) Provide information, when appropriate, that is useful to other staff working directly with the resident; and

(2) Include evaluative and summary reports in the resident's record kept in the living unit.

(b) Continuing observations of treatment progress must be—

(1) Recorded accurately, summarized, and communicated; and

(2) Used in evaluating progress.

§ 442.498 Staff and facilities.

(a) The ICF/MR must have available enough qualified staff and support personnel to carry out the various speech pathology and audiology services, in accordance with stated goals and objectives.

(b) Staff who assume independent responsibilities for clinical services must meet the qualification requirements of § 405.1101 of this chapter.

(c) The ICF/MR must provide adequate, direct, and continuing supervision to personnel, volunteers, or support personnel used in providing clinical services.

(d) The ICF/MR must have enough space, equipment, and supplies to provide efficient and effective speech pathology and audiology services.

RECORDS

§ 442.499 Maintenance of resident records.

(a) The ICF/MR must maintain a record for each resident that is adequate for—

(1) Planning and continuous evaluation of the resident's habilitation program;

(2) Furnishing documentary evidence of each resident's progress and response to his habilitation program; and

(3) Protecting the legal rights of the residents, the ICF/MR, and the staff.

(b) Any individual who makes an entry in a resident's record must make it legibly, date it, and sign it.

(c) The ICF/MR must provide a legend to explain any symbol or abbreviation used in a resident's record.

§ 442.500 Admission records.

At the time a resident is admitted, the ICF/MR must enter in the individual's record the following information:

(a) Name, date of admission, birth date and place, citizenship status, marital status, and social security number.

(b) Father's name and birthplace, mother's maiden name and birthplace, and parents' marital status.

(c) Name and address of parents, legal guardian, and next of kin if needed.

(d) Sex, race, height, weight, color of hair, color of eyes, identifying marks, and recent photograph.

(e) Reason for admission or referral problem.

(f) Type and legal status of admission.

(g) Legal competency status.

(h) Language spoken or understood.

(i) Sources of support, including social security, veterans' benefits, and insurance.

(j) Religious affiliation, if any.

(k) Reports of the preadmission evaluations.

(l) Reports of previous histories and evaluations, if any.

§ 442.501 Record entries during residence.

(a) Within 1 month after the admission of each resident, the ICF/MR must enter in the resident's record—

(1) A report of the review and updating of the preadmission evaluation;

(2) A prognosis that can be used for programing and placement; and

(3) A comprehensive evaluation and individual program plan, designed by an interdisciplinary team.

(b) the ICF/MR must enter the following information in a resident's record during his residence:

(1) Reports of accidents, seizures, illnesses, and treatments for these conditions.

(2) Records of immunizations.

(3) Records of all periods that restraints were used, with justification and authorization for each.

(4) Reports of regular, at least annual, review and evaluation of the program, developmental progress, and status of each resident.

(5) Enough observations of the resident's response to his program to enable evaluation of its effectiveness.

(6) Records of significant behavior incidents.

(7) Records of family visits and contacts.

(8) Records of attendance and absences.

(9) Correspondence pertaining to the resident.

(10) Periodic updates of the information recorded at the time of admission.

(11) Appropriate authorizations and consents.

(c) The ICF/MR must enter a discharge summary* in the resident's record at the time he is discharged.

§ 442.502 Confidentiality.

(a) The ICF/MR must keep confidential all information contained in a resident's records, including information contained in an automated data bank.

(b) The record is the property of the ICF/MR which must protect it from loss, damage, tampering, or use by unauthorized individuals.

(c) The ICF/MR must have written policies governing access to, duplication of, and release of information from the record.

(d) The ICF/MR must obtain written consent of the resident, if competent, or his guardian before it releases information to individuals not otherwise authorized to receive it.

§ 442.503 Central record service.

The ICF/MR must—

(a) Maintain an organized central record service for the collection and release of resident information;

(b) Make records readily accessible to authorized personnel if a centralized system is used;

(c) Have appropriate records available in the resident living units;

(d) Have a master alphabetical index of all residents admitted to the ICF/MR; and

(e) Retain records for a period consistent with HEW regulations and the statute of limitations of the State in which the ICF/MR is located.

§ 442.504 Staff and facilities.

The ICF/MR must have—

(a) Enough qualified staff and support personnel to accurately process, check, index, file, and retrieve records and record data promptly; and

(b) Adequate space, equipment, and supplies to provide efficient and effective record services.

SAFETY AND SANITATION

§ 442.505 Emergency plan and procedures.

(a) The ICF/MR must have a written staff organization plan and detailed written procedures to meet all potential emergencies and disasters such as fire, severe weather, and missing residents.

(b) The ICF/MR must—

(1) Clearly communicate and periodically review the plan and procedures with the staff; and

(2) Post the plan and procedures at suitable locations through the facility.

§ 442.506 Evacuation drills.

(a) The ICF/MR must hold evacuation drills at least quarterly for each shift of personnel and under varied conditions to—

(1) Insure that all personnel on all shifts are trained to perform assigned tasks;

(2) Insure that all personnel on all shifts are familiar with the use of the ICF/MR's firefighting equipment; and

(3) Evaluate the effectiveness of emergency and disaster plans and procedures.

(b) The ICF/MR must—

(1) Actually evacuate residents to safe areas during at least one evacuation drill each year, on each shift;

(2) Make special provisions for the evacuation of the physically handicapped, such as fire chutes and mattressloops with poles;

(3) Write and file a report and evaluation of each evacuation drill; and

(4) Investigate all accidents and take corrective action to prevent similar accidents in the future.

§ 442.507 Fire protection.

(a) Except as provided in §§ 442.508, 442.509, and paragraph (b) of this section, the ICF/MR must meet the provisions of the Life Safety Code of the National Fire Protection Association, 1967 edition, that apply to institutional occupancies.

(b) If the Secretary finds that the State has a fire and safety code imposed by State law that adequately protects residents in ICF's/MR, the State survey agency may apply the State code for purposes of medicaid certification instead of the Life Safety Code.

§ 442.508 Fire protection exceptions for smaller ICF's/MR.

The State survey agency may apply the lodgings or rooming houses section of the residential occupancy requirements of the Life Safety Code of the National Fire Protection Association, 1967 edition, instead of the institutional occupancy provisions required by § 442.507, to an ICF/MR that has 15 beds or less if a physician or psychologist who meets the definition of qualified mental retardation professional under § 442.401 certifies that each resident is—

(a) Ambulatory;

(b) Receiving active treatment; and

(c) Capable of following directions and taking appropriate action for self-preservation under emergency conditions.

§ 442.509 Fire protection waivers.

(a) The State survey agency may waive specific provisions of the Life Safety Code required by § 442.507, for as long as it considers appropriate, if—

(1) The waiver would not adversely affect the health and safety of the residents;

(2) Rigid application of specific provisions would result in unreasonable hardship for the ICF/MR as determined under guidelines contained in the HCFA long-term care manual; and

(3) The waiver is granted in accordance with criteria contained in the long-term care manual.

(b) If a State agency waives provisions of the Code for an existing building of two or more stories that is not built of at least 2-hour fire-resistive construction, the ICF/MR may not house a blind, nonambulatory, or physically handicapped resident above the street-level floor unless it is built of—

(1) One-hour protected, noncumbustible construction as defined in National Fire Protection Association Standard No. 220;

(2) Full sprinklered, 1-hour protected, ordinary construction;

(3) Full sprinklered, 1-hour protected, wood frame construction.

§ 442.510 Paint.

The ICF/MR must—

(a) Use lead-free paint inside the facility; and

(b) Remove or cover old paint or plaster containing lead so that it is not accessible to residents.

§ 442.511 Building accessibility and use.

(a) The ICF/MR must—

(1) Be accessible to and usable by all residents, personnel, and the public, including individuals with disabilities; and

(2) Meet the requirements of American National Standards Institute (ANSI) Standard No. A117.1 (1961) American Standard Specifications for Making Buildings and Facilities Accessible to and Usable by the Physically Handicapped.

(b) The State survey agency may waive, for as long as it considers appropriate, specific provisions of ANSI Standard No. A117.1 (1961) if—

(1) The construction plans for the ICF/MR or a part of it were approved and stamped by the responsible State agency before March 18, 1974;

(2) The provision would result in unreasonable hardship on the ICF/MR if strictly enforced; and

(3) The waiver does not adversely affect the health and safety of the residents.

§ 442.512 Sanitation records and reports.

The ICF/MR must keep—

(a) Records that document compliance with the sanitation, health, and environmental safety codes of the State or local authorities having primary jurisdiction over the ICF/MR; and

(b) Written reports of inspections by State or local health authorities, and records of action taken on their recommendations.

ADMINISTRATIVE SERVICES

§ 442.513 Support services.

(a) The ICF/MR must provide adequate, modern administative support to efficiently meet the needs of residents and facilitate attainment of the ICF/MR's goals and objectives.

(b) The ICF/MR must—

(1) Document its purchasing process;

(2) Adequately operate its inventory control system and stockroom;

(3) Have appropriate storage facilities for all supplies and surplus equipment; and

(4) Have enough trained and experienced personnel to do purchase, supply, and property control functions.

§ 442.514 Communication system.

(a) The ICF/MR must have an adequate communication system, including telephone service, that insures—

(1) Prompt contact of onduty personnel; and

(2) Prompt notification of responsible personnel in an emergency.

§ 442.515 Engineering and maintenance.

The ICF/MR must have—

(a) An appropriate, written preventive maintenance program; and

(b) Enough trained and experienced personnel for engineering and maintenance functions.

§ 442.516 Laundry services.

The ICF/MR must manage its laundry services so that it meets daily clothing and linen needs without delay.

PART 447—PAYMENTS FOR SERVICES

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AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—Payments: General Provisions

§ 447.1 Purpose.

This subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State medicaid agencies for medicaid services.

§ 447.10 Prohibition against reassignment of provider claims.

(a) *Basis and purpose.* This section implements sec. 1902(a)(32) of the Act which prohibits State payments for medicaid services to anyone other than a provider or recipient, except in specified circumstances.

(b) *Definitions.* For purposes of this section:

"Facility" means an institution that furnishes health care services to inpatients.

"Factor" means an individual or an organization, such as a collection agency or service bureau, that advances money to a provider for accounts receivable that the provider has assigned, sold or transferred to the individual organization for an added fee or a deduction of a portion of the accounts receivable. Factor does not include a business representative as described in paragraph (f) of this section.

"Organized health care delivery system" means a public or private organization for delivering health services. It includes, but is not limited to, a clinic, a group practice prepaid capitation plan, and a health maintenance organization.

(c) *State plan requirements.* A State plan must provide that the requirements of paragraphs (d) through (h) are met.

(d) *Who may receive payment.* Payment may be made only—

(1) To the provider; or

(2) To the recipient if he is a noncash recipient eligible to receive the payment under § 447.25; or

(3) In accordance with paragraphs (e), (f), and (g) of this section.

(e) *Reassignments.* Payment may be made in accordance with a reassignment from the provider to a government agency or reassignment by a court order.

(f) *Business agents.* Payment may be made to a business agent, such as a billing service or an accounting firm, that furnishes statements and receives payments in the name of the provider, if the agent's compensation for this service is—

(1) Related to the cost of processing the billing;

(2) Not related on a percentage or other basis to the amount that is billed or collected; and

(3) Not dependent upon the collection of the payment.

(g) *Individual practitioners.* Payment may be made to—

(1) The employer of the practitioner, if the practitioner is required as a condition of employment to turn over fees to the employer;

(2) The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or

(3) A foundation, plan, or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

(h) *Prohibition of payment to factors.* Payment for any service furnished to a recipient by a provider may not be made to or through a factor, either directly or by power of attorney.

§ 447.15 Acceptance of State payment as payment in full.

A State plan must provide that the medicaid agency must limit participation in the medicaid program to providers who accept, as payment in full, the amounts paid by the agency. (Sec. 1902(a)(4) of the Act.)

§ 447.25 Direct payments to certain recipients for physicians' or dentists' services.

(a) *Basis and purpose.* This section implements sec. 1905(a) of the Act by prescribing requirements applicable to States making direct payments to certain recipients for physicians' or dentists' services.

(b) *State plan requirements.* Except for groups specified in paragraph (c) of this section, a State may make direct payments to recipients for physicians' or dentists' services. If it does so, the State plan must—

(1) Provide for direct payments; and

(2) Specify the conditions under which payments are made.

(c) *Federal financial participation.* No FFP is available in expenditures for direct payment for physicians' or dentists' services to any recipient—

(1) Who is receiving assistance under the State's approved plan under title I, IV-A, X, XIV or XVI (AABD) of the Act; or

(2) To whom supplemental security benefits are being paid under title XVI of the Act; or

(3) Who is receiving or eligible for a State supplementary payment or would be eligible if he were not in a medical institution, and who is eligible for medicaid as a categorically needy recipient.

(d) *Federal requirements.* (1) Direct payments to recipients under this section are an alternative to payments directly to providers and are subject to the same conditions; for example, the State's reasonable charge schedules are applicable.

(2) Direct payments must be supported by providers' bills for services.

§ 447.30 Suspension of payments to former medicare providers with unresolved overpayments.

(a) *Basis and purpose.* This section implements sec. 1903(j) of the Act, which provides for the suspension of FFP for medicaid payments to an institution if that institution has not arranged to repay medicare overpayments or has failed to provide information to determine the amount of the overpayments.

(b) *When suspension occurs.* The Administrator may suspend medicaid payments to a State for an institution that—

(1) Does not have in effect, when the suspension is made, a medicare provider agreement with the Secretary under sec. 1866 of the Act and part 405, subpart F of this chapter;

(2) Did have a medicare provider agreement in effect, before the Administrator suspended payment; and

(3) Has failed either to—

(i) Repay or make satisfactory arrangements with the Administrator to repay medicare overpayments made to it; or

(ii) Submit appropriate information to enable the Administrator to determine the amount of medicare overpayments, if any.

(c) *Notice of suspension.* (1) When the Administrator suspends payments under this subpart, he will notify the medicaid agency of each State that he believes may use the institution's services under medicaid.

(2) The Administrator will send the notice by certified mail, return receipt requested.

(d) *Effective date of suspension.* Suspension of payment will become effective on the 60th day after the day on which the agency receives notice of suspension.

(e) *Termination of suspension.* The Administrator will terminate the suspension if he determines that—

(1) The institution is participating in substantial negotiations to remedy the conditions that gave rise to the order;

(2) Medicare overpayments are no longer due from the institution; or

(3) The institution has made a satisfactory arrangement to repay the amount it owes.

(f) *Notice of termination.* The Administrator will notify each State that previously received notice of the suspension that the suspension has been terminated.

(g) *Duration of FFP suspension.* No FFP is available in expenditures for services that are provided by a suspended institution from the date on which the suspension becomes effective until the first day of the month in which the suspension is terminated.

§ 447.35 Limits on FFP for capital expenditures.

(a) *Basis and purpose.* (1) Sec. 1122 of the Act provides for exclusion from FFP of expenses related to certain capital expenditures. The cost containment and quality control regulations of the Public Health Service (part 100 of this title) concern agreements between the Secretary and the States under sec. 1122, procedures for reviewing proposed capital expenditures, and determinations by the Secretary as to allowability of expenses related to capital expenditures.

(2) This section identifies categories of expenses for which FFP is not available under medicaid if a State has an agreement under sec. 1122 and the Secretary has determined under sec. 1122 and part 100 that the expenses are not allowable.

(b) *FFP limits.* Except as provided in § 100.108(b) of this title, no FFP is available in expenses related to a capital expenditure if the Secretary determines that—

(1) The State designated planning agency had not been given timely written notice of a capital expenditure in accordance with § 100.106 of this title; or

(2) The planning agency has, under sec. 1122 and part 100 of this title, submitted to the Secretary its finding that the proposed expenditure is not consistent with the standards, criteria or plans described in § 100.104(a)(2) of this title.

(c) *Expenses related to a capital expenditure.* Expenses related to a capital expenditure include the following, regardless of the manner in which the expenses are recorded in the provider's records and cost report:

(1) Depreciation.

(2) Interest on borrowed funds.

(3) A return on equity capital (in the case of proprietary facilities).

(4) Other costs of activities that are essential to the acquisition, improvement, modernization, expansion, or replacement of the plant, buildings, and equipment with respect to which the expenditure is made, including, but not limited to—

(i) Studies, surveys, designs, plans, working drawings, and specifications;

(ii) Transportation;

(iii) Installation and start-up expenses;

(iv) In-transit insurance;

(v) Costs of grading and paving;

(vi) Taxes assessed during the construction period;

(vii) Costs of demolishing or razing structures on land;

(viii) Title fees;

(ix) Permit and license fees;

(x) Broker commissions;

(xi) Architectural, legal, accounting, and appraisal fees; and

(xii) Interest, finance, or carrying charges on bonds, notes, and other costs incurred for borrowing funds.

(d) *FFP for costs of conformity determination.* FFP is available in expenditures for reasonable costs incurred by a provide to determine whether a proposed capital expenditure is in conformity with applicable standards, cri-

teria, or plans for adequate health care resources in the area. However, no FFP is available if the provider makes the capital expenditure without the approval required by part 100 of this title.

(e) *Exclusion of expenses related to capital expenditures: Payment on a reasonable cost or cost-related basis.* If payment is made on a reasonable cost or cost-related basis, expenses related to capital expenditures that are not available for FFP must be specifically excluded from allowable cost computations.

(f) *Exclusion of expenses related to capital expenditures: Payment on other than a reasonable cost or cost-related basis.* If payment is made on a per capita, fixed fee, negotiated rate, or any other basis (other than reasonable cost or cost-related), expenses related to capital expenditures that are not available for FFP must be excluded from the payment rate as follows:

(1) For a facility that participates in the medicare program, the State shall—

(i) Compute the percentage difference between the medicare allowable costs before and after the deduction of unallowed expenses; and

(ii) Reduce the medicaid payment rate to the facility by that percentage.

(2) For a facility that does not participate in the medicare program, the State must reduce the payment rate by an estimated amount. The estimate is based upon a comparative analysis of the facility's expenses related to capital expenditures as reflected in the facility's periodic financial statements. For example, the State may compute the percentage difference between the facility's expenses related to capital expenditures as recorded in its financial statements and those expenses less the amounts for which FFP is not available, and reduce the payment rate by that percentage.

(g) *Equivalent deduction if a facility is obtained by a lease.* If a person obtained by lease or comparable arrangement any facility, part of a facility, or equipment for a facility that would have been considered a capital expenditure if the person had purchased it—

(1) In determining payments for services furnished in that facility, an amount must be deducted from rental expense which is a reasonable equivalent of the amount that would have been excluded if the person had purchased the facility or equipment; and

(2) In computing the person's return on equity capital, any amount deposited under the terms of the lease or comparable arrangement must be deducted from that return.

(h) *Capital assets acquired by donation or exchange.* If a person acquired by donation or exchange any facility, part of a facility, or equipment for a facility that would have been considered a capital expenditure if the person had purchased it, the acquisition is treated as a capital expenditure for purposes of excluding expenses related to capital expenditures.

(i) *Reconsideration of FFP determination.* (1) Any person or State adversely affected by a determination by the Secretary under sec. 1122 of the Act, this subpart or part 100 of this title may, within 6 months of the date of the determination, request the Secretary to reconsider the determination. A determination by the Secretary under sec. 1122 of the Act is not subject to administrative or judicial review.

(2) A State is also entitled upon request to receive a reconsideration of a disallowance under this subpart, in accordance with sec. 1116(d) of the Act and 45 CFR part 16.

§ 447.40 Payments for reserving beds in institutions.

(a) The medicaid agency may make payments to reserve a bed during a recipient's temporary absence from an inpatient facility, if—

(1) The recipient's plan of care provides for absences other than for hospitalization; and

(2) The State plan provides for such payments and describes any limitations on the reserved bed policy.

(b) An agency that pays for reserved beds in an inpatient facility may pay less for a reserved bed than an occupied bed if there is a cost differential between the two beds. (Sec. 1102 of the Act.)

COST SHARING

§ 447.50 Cost sharing: Basis and purpose.

(a) Section 1902(a)(14) of the Act permits States to require certain recipients to share some of the costs of medicaid by imposing upon them such payments as enrollment fees, premiums, deductibles, coinsurance, co-payments, or similar cost sharing charges. For States that impose cost sharing payments, §§ 447.51–59 prescribe State plan requirements and options for cost sharing, specify the standards and conditions under which States may impose cost sharing, set forth minimum amounts and the methods for determining maximum amounts, and prescribe conditions for FFP that relate to cost sharing requirements.

ENROLLMENT FEE, PREMIUM OR SIMILAR COST SHARING CHARGE

§ 447.51 Requirements and options.

(a) The plan must provide that the medicaid agency does not impose any enrollment fee, premium, or similar charge upon categorically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(b) The plan may impose an enrollment fee, premium, or similar charge on medically needy individuals, as defined in §§ 435.4 and 436.3 of this subchapter, for any services available under the plan.

(c) For each charge imposed under paragraph (b) of this section, the plan must specify—

(1) The amount of the charge;

(2) The period of liability for the charge; and

(3) The consequences for an individual who does not pay.

(d) The plan must provide that any charge imposed under paragraph (b) of this section is related to total gross family income as set forth under § 447.52.

§ 447.52 Minimum and maximum income-related charges.

For the purpose of relating the amount of an enrollment fee, premium, or similar charge to total gross family income, as required under § 447.51(d), the following rules apply:

(a) *Minimum charge.* A charge of at least $1.00 per month is imposed on each—

(1) One- or two-person family with monthly gross income of $150 or less;

(2) Three- or four-person family with monthly gross income of $300 or less; and

(3) Five- or more-person family with monthly gross income of $350 or less.

(b) *Maximum charge.* Any charge related to gross family income that is above the minimum listed in paragraph (a) of this section may not exceed the standards shown in the following table:

Maximum Monthly Charge

Gross family income (per month)	Family size		
	1 or 2	3 or 4	5 or more
$150 or less	$1	$1	$1
$151 or $200	2	1	1
$201 to $250	3	1	1
$251 to $300	4	1	1
$301 to $350	5	2	1
$351 to $400	6	3	2
$401 to $450	7	4	3
$451 to $500	8	5	4
$501 to $550	9	6	5
$551 to $600	10	7	6
$601 to $650	11	8	7
$651 to $700	12	9	8
$701 to $750	13	10	9
$751 to $800	14	11	10
$801 to $850	15	12	11
$851 to $900	16	13	12
$901 to $950	17	14	13
$951 to $1,000	18	15	14
$More than $1,000	19	16	15

DEDUCTIBLE, COINSURANCE, CO-PAYMENT OR SIMILAR COST-SHARING CHARGE

§ 447.53 Applicability; specifications; multiple charges.

(a) *Categorically needy.* (1) The plan must provide that the medicaid agency does not impose any deductible, coinsurance, co-payment, or similar charge upon categorically needy individuals for those services listed in §§ 440.40-440.50 and 440.70 of this subchapter. These services are inpatient and outpatient hospital services; rural health clinic services; other laboratory and X-ray services; skilled nursing facility services for individuals 21 years of age or older; early and periodic screening, diagnosis and treatment of individuals under the age of 21; family planning services and supplies for individuals of child-bearing age; physicians' services; and home health care services.

(2) The plan may impose a deductible, coinsurance, co-payment, or similar charge upon categorically needy individuals for any other service under the plan.

(b) *Medically needy.* The plan may impose a deductible, coinsurance, co-payment or similar charge upon medically needy persons for any service under the plan.

(c) *Prohibition against multiple charges.* For any service, the plan may not impose more than one type of charge referred to in paragraph (a)(2) and (b) of this section.

(d) *State plan specifications.* For each charge imposed under this section, the plan must specify—

(1) The service for which the charge is made;

(2) The amount of the charge; and

(3) The basis for determining the charge.

§ 447.54 Maximum allowable charges.

(a) *Non-institutional services.* For non-institutional services, the plan must provide that—

(1) Any deductible it imposes does not exceed $2.00 per month per family for each period of medicaid eligibility. For example, if medicaid eligibility is certified for a 3-month period, the maximum deductible which may be imposed on a family for that period of eligibility is $6.00;

(2) Any coinsurance rate it imposes does not exceed 5 percent of the payment the agency makes for the services; and

(3) Any co-payments it imposes do not exceed the amounts shown in the following table:

State's payment for the service:	*Maximum co-payment chargeable to recipient*
$10 or less	$.50
$11 to $25	1.00
$26 to $50	2.00
$51 or more	3.00

(b) *Institutional services.* For institutional services, the plan must provide that the maximum deductible, coinsurance or co-payment charge for each admission does not exceed 50 percent of the payment the agency makes for the first day of care in the institution.

(c) *Cumulative maximum.* The plan may provide for a cumulative maximum amount for all deductible, coinsurance or co-payment charges that it imposes on any family during a specified period of time.

§ 447.55 Standard co-payment.

(a) The plan may provide for a standard, or fixed, co-payment amount for any service.

(b) This standard copayment amount for any service may be determined by applying the maximum co-payment amounts specified in §447.54 (a) and (b) to the agency's average or typical payment for that service. For example, if the agency's typical payment for prescribed drugs is $4 to $5 per prescription, the agency might set a standard copayment of $0.50 per prescription.

§ 447.56 Income-related charges.

Subject to the maximum allowable charges specified in § 447.54 (a) and (b), the plan may provide for income-related deductible, coinsurance or co-payment charges. For example, an agency may impose a higher charge on medically needy recipients than it imposes upon categorically needy recipients.

§ 447.57 Restrictions on payments to providers.

(a) The plan must provide that the agency does not increase the payment it makes to any provider to offset uncollected amounts for deductibles, coinsurance, copayments or similar charges that the provider has waived or are uncollectable, except as permitted under paragraph (b) of this section.

(b) For those providers that the agency reimburses under medicare reasonable cost reimbursement principles, in accordance with subpart B of this part, an agency may increase its payment to offset uncollected deductible, coinsurance, copayment, or similar charges that are bad debts of providers.

§ 447.58 Payments to prepaid capitation organizations.

If the agency contracts with a prepaid capitation organization that does not impose the agency's deductibles, coinsurance, copayments or similar charges on its recipient members, the plan must provide that the agency calculates its payments to the organization as if those cost sharing charges were collected.

FEDERAL FINANCIAL PARTICIPATION

§ 447.59 FFP: Conditions relating to cost sharing.

No FFP in the State's expenditures for services is available for—

(a) Any cost sharing amounts that recipients should have paid as enrollment fees, premiums, deductibles, coinsurance, copayments, or similar charges under § 447.50-58 (except for amounts that the agency pays as bad debts of providers under § 447.57); and

(b) Any amounts paid by the agency on behalf of ineligible individuals, whether or not the individual had paid any required premium or enrollment fee.

Subpart B—Payment Methods: General Provisions

§ 447.200 Basis and purpose.

This subpart prescribes State plan requirements for setting payment rates to implement, in part, section 1902(a)(30) of the act, which requires that payments for services do not exceed reasonable charges consistent with efficiency, economy, and quality of care.

§ 447.201 State plan requirements.

(a) A State plan must provide that the requirements in this subpart are met.

(b) The plan must describe the policy and the methods to be used in setting payment rates for each type of service included in the State's medicaid program.

§ 447.202 Audits.

The medicaid agency must assure appropriate audit of records if payment is based on costs of services or on a fee plus cost of materials.

§ 447.203 Documentation of payment rates.

(a) The agency must maintain documentation of payment rates and make it available to HEW upon request.

(b) The agency must record, in State manuals or other official files, the following information for increases in payment rates for individual practitioner services:

(1) An estimate of the percentile of the range of customary charges to which the revised payment structure equates and a description of the methods used to make the estimate.

(2) An estimate of the composite average percentage increase of the revised payment rates over the preceding rates.

§ 447.204 Encouragement of provider participation.

The agency's payments must be sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population.

Subpart C—Payment Methods and Upper Limits for Specific Services

§ 447.250 Basis and purpose.

Section 447.261 of this subpart implements section 1902(a)(13)(D) of the act, which requires that the State plan provide for payment of the reasonable cost of inpatient hospital services. Sections 447.272 through 447.311 implement section 1902(a)(13)(E) of the act, which requires that the State plan provide for payment for long-term care facility services on a reasonable cost-related basis. Sections 447.251, 447.252, 447.262, and 447.315 through 447.361 implement section 1902(a)(30) of the act, which requires that payments must not exceed reasonable charges consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the act, which requires that the State plan provide for payment for rural health clinic services in accordance with regulations prescribed by the Secretary.

§ 447.251 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

§ 447.252 Adherence to upper limits; FFP.

(a) The medicaid agency must not pay more than the upper limits described in this subpart.

(b) The upper limits do not apply to payments made under the plan for deductibles and coinsurance imposed under medicare. Deductible and coinsurance payments may be made up to the reasonable charge under medicare.

(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

NOTE.—The Secretary may waive any limitation on reimbursement imposed by subpt. C of this part for experiments conducted under sec. 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by sec. 222(b) of Pub. L. 92-603, and under sec. 222(a) of Pub. L. 92-603.

INPATIENT HOSPITAL SERVICES

§ 447.261 Reasonable cost payment for inpatient hospital services.

(a) The medicaid agency must pay the reasonable cost of inpatient hospital services under methods and standards developed by the State and approved by the Regional Medicaid Director before implementation.

(b) The methods and standards must—

(1) Be consistent with the capital expenditure provisions of section 1122 of the Act, as specified in § 447.35, if the State has an agreement under those provisions; and

(2) Adopt the medicare standards and principles for determining reasonable cost reimbursement in §§ 405.402 through 405.455 of this chapter or, as an alternative, meet the criteria in paragraph (d) of this section.

(c) if the medicare standards and principles are adopted, they must be modified to—

(1) Exclude the inpatient routine nursing salary cost differential under § 405.430 of this chapter; and

(2) Apply the limits established by the Secretary under § 405.460 of this chapter.

(d) If the medicare standards and principles are not adopted, the alternative methods and standards must meet all of the following criteria:

(1) They provide incentives for efficiency and economy.

(2) They provide for payment rates that are no higher than the amounts that would be determined using medicare principles of cost reimbursement, as modified by paragraph (c) of this section.

(3) They assure adequate participation of hospitals in the State's medicaid program and the availability of hospital services of high quality to recipients.

(4) They afford providers and other interested members of the public an opportunity to review and comment on proposed methods and standards before they are submitted as State plan amendments.

(5) They provide for keeping a written record of the comments and the consideration given to them.

(6) At a minimum, they afford individual providers an opportunity to submit evidence and obtain prompt administrative review of payment rates set for them if—

(i) Costs of capital improvements were approved by a State's planning agency after the payment rates were set, and those costs were not considered in the rate calculation;

(ii) Costs of improvements were incurred because of certification or licensing requirements established after the payment rates were set, and those costs were not considered in the rate calculation; or

(iii) Incorrect data were used or an error was made in the rate calculation.

(7) They provide for documentation that is adequate to evaluate experience under the approved methods and standards.

§ 447.262 Upper limits: Inpatient hospital services.

The agency must not pay a provider of inpatient hospital services more than the lower of—

(1) The reasonable cost of services determined under this subpart; or

(2) The provider's customary charges to the general public.

REASONABLE COST-RELATED PAYMENT FOR LONG-TERM CARE FACILITY SERVICES

§ 447.272 Definitions.

For the purposes of §§ 450.271-450.316—

"Accrual method of accounting" means that revenue is reported in the period when it is earned, regardless of when it is collected, and expenses are reported in the period in which they are incurred, regardless of when they are paid.

"Bad debts" are amounts considered to be uncollectable from accounts and notes receivable for services provided.

"Cash method of accounting" means that revenues are recognized only when cash is received, and expenditures for expense and asset items are not recorded until cash is disbursed for them.

"Charity allowances" are reductions in the provider's charges because of the patient's indigence or medical indigence.

"Cost finding" means the process of recasting the data derived from the accounts ordinarily kept by a provider to determine costs of each type of service by allocating direct costs and prorating indirect costs.

"Courtesy allowances" are a reduction in the provider's charges in the form of an allowance to physicians, clergy, and others. Employee fringe benefits, such as hospitalization and personnel health programs, not are courtesy allowances.

"Generally accepted accounting principles" means accounting principles approved by the American Institute of Certified Public Accountants.

"Generally accepted auditing standards" means auditing standards approved by the American Institute of Certified Public Accountants.

"Long-term care facility services" means skilled nursing care facility services and intermediate care facility services.

"Provider" means a provider of skilled nursing facility or intermediate care facility services.

"Retrospective payment system" means a system in which payment is made on the basis of a provisional payment rate set prospectively for an accounting period, and in which payments may be retrospectively adjusted on the basis of the cost experience during the accounting period.

§ 447.273 Reasonable cost-related basis for long-term care facility services.

The medicaid agency must pay for long-term care facility services on a reasonable cost-related basis in accordance with §§ 447.274 through 447.311.

COST FINDING AND REPORTING

§ 447.274 Provider cost reports.

(a) No later than 3 months after the close of the cost reporting year, each provider must submit a cost report to the medicaid agency.

(b) The cost report must include—

(1) An itemized list of the provider's allowable costs under §§ 447.278-447.284 for the cost reporting year or for the period of participation in the plan if less than a full year; and

(2) A list of the costs of the various services provided under the plan, as determined by applying the agency's approved cost-finding method to the provider's allowable costs.

(c) The itemized list of allowable costs must be compiled on the basis of generally accepted accounting principles and the accrual method of accounting. The cash method of accounting is acceptable for public institutions.

(d) There must be a uniform cost report form for all skilled nursing facilities (SNF's) and a uniform cost report form for all intermediate care facilities (ICF's). However, the same form may be used by both SNF's and ICF's.

§ 447.275 Dates of cost reporting year.

(a) The State plan must specify the inclusive dates of the cost reporting year. The year need not be the same for all providers.

(b) The plan must specify the beginning date of the first cost reporting year, which must be no later than January 1, 1977.

§ 447.276 Cost-finding method.

(a) The plan must specify the cost-finding method or methods to be used by providers.

(b) There must be a uniform method for all SNF's and a uniform method for all ICF's. The same method may be used by both.

(c) The cost-finding method must be approved by the Regional Medicaid Director. Medicare cost-finding methods specified under § 405.453(d) of this chapter will be approved automatically. The Regional Medicaid Director may approve other cost-finding methods.

§ 447.277 Recordkeeping.

(a) Each provider must keep its financial and statistical records for the cost reporting year for at least 3 years after the date of submission of the cost report form to the medicaid agency.

(b) The records must be accurate and in sufficient detail to substantiate the costs reported under § 447.274.

(c) Each provider must make the records available on request to representatives of the agency or HEW.

(d) The agency must keep all costs reports for at least 3 years after it receives them from providers.

§ 447.278 Items of expense included in allowable cost: General provisions.

The plan must specify the items of expense that are allowable costs.

§ 447.279 Cost of meeting certification standards.

Allowable costs for SNF's and ICF's include all items of expense providers must incur—

(a) To meet the definition of SNF services or ICF services in § 440.40(a) or § 440.150 of this subchapter;

(b) To comply with the standards for SNF's or ICF's in part 442 of this subchapter;

(c) To comply with requirements established by the State agency responsible for establishing and maintaining health standards under § 431.610 of this subchapter; and

(d) To comply with any other requirements for licensing under State law that must be met to provide SNF or ICF services.

§ 447.281 Costs of routine services.

(a) Allowable costs include all items of expense that providers incur in providing routine services.

(b) "Routine services" means regular room, dietary and nursing services; minor medical and surgical supplies; and the use of equipment and facilities.

(c) The following are examples of expenses that allowable costs for routine services must include:

(1) All general nursing services, including but not limited to administration of oxygen and related medications, handfeeding, incontinency care, tray service, and enemas.

(2) Items furnished routinely and relatively uniformly to all patients, such as patient gowns, water pitchers, basins, and bedpans.

(3) Items stocked at nursing stations or on the floor in gross supply and distributed or used individually in small quantities such as alcohol, applicators, cotton balls, bandaids, antacids, aspirin (and other nonlegend drugs ordinarily kept on hand), suppositories, and tongue depressors.

(4) Items used by individual patients but which are reusable and expected to be available, such as ice bags, bedrails, canes, crutches, walkers, wheelchairs, traction equipment, and other durable medical equipment;

(5) Special dietary supplements used for tube feeding or oral feeding, such as elemental high nitrogen diet, even if written as a prescription item by a physician (because these supplements have been classified by the Food and Drug Administration as a food rather than a drug);

(6) Laundry services other than for personal clothing.

§ 447.282 Bad debts.

Allowable costs include only bad debts that are attributed to cost sharing amounts as defined in §§ 447.50-447.59.

§ 447.283 Items of expenses not included in allowable costs.

Allowable costs do not include charity and courtesy allowances.

§ 447.284 Purchases from related organizations: Limit on costs.

(a) Costs of services, facilities, and supplies furnished by organizations related to the provider by common ownership or control must not exceed the lower of the cost to the organization or the price of comparable services, facilities, or supplies purchased elsewhere.

(b) The cost report must identify related organizations and costs.

AUDITS

§ 447.290 Audit procedures.

The plan must describe the State's procedures for audits.

§ 447.291 Cost report desk analysis.

The agency must analyze each cost report within 6 months of its receipt to verify, to the extent possible, that the provider has complied with § 447.274.

§ 447.292 Onsite audits and exemption.

(a) The agency must provide for an onsite audit of the financial and statistical records of at least one-third of the providers each year of a 3-year period that begins at the close of the first cost reporting year (see § 447.275). All providers must be audited within the 3-year period.

(b) The Regional Medicaid Director may exempt a State from paragraph (a) of this section if—

(1) The State has a continuing audit program;

(2) The agency has completed onsite audits of the financial and statistical records of all providers during the 3-year period preceding the end of the first cost reporting period; and

(3) Each onsite audit was conducted in accordance with generally accepted auditing standards and was sufficiently comprehensive in scope to determine—

(i) That only proper items of cost applicable to medicaid services were in the provider's calculation of its costs; and

(ii) Whether expenses attributable to the items of cost were accurately determined and reasonable.

§ 447.293 Continuing audits.

(a) Each year the agency must provide for onsite audit of the financial and statistical records of at least 15 percent of participating facilities selected as follows:

(1) At least 5 percent of participating facilities selected at random.

(2) At least 10 percent of participating facilities selected by profiles of costs or other factors established by the agency.

(b) These yearly audits must begin in the fourth year after the first cost reporting year. However, for a State exempted from onsite audits under § 447.292, these audits must begin in the year after the first cost reporting year.

§ 447.294 Audit standards.

(a) Audits must meet generally accepted auditing standards. The adoption of the audit standards in Health Insurance Manual (HIM-18), issued under the medicare program, is recommended, but the agency may establish its own standards.

(b) Audits of providers' cost reports, financial records, and other pertinent documents must be adequate to verify——

(1) That the provider has included only those expense items that the agency has specified as allowable costs under § 450.278 in compiling the costs of services;

(2) That the provider has accurately determined allowable costs under § 447.274(b)(1);

(3) That the provider has accurately attributed allowable costs to cost of services under § 447.274(b)(2); and

(4) That the provider's allowable costs are reasonable.

§ 447.295 Audit report.

(a) Upon conclusion of each audit under §§ 447.292 the auditor must submit an audit report to the agency.

(b) The report must meet generally accepted auditing standards.

(c) The report must state the auditor's opinion as to whether, in all material respects, the cost report submitted by the provider under § 447.274 complies with § 447.294(b) (1) and (2).

(d) The agency must keep audit reports for at least 3 years after receipt.

§ 447.296 Accounting for overpayment found in audits.

The agency must account for overpayments found in audits on the quarterly statement of expenditures no later than the second quarter following the quarter in which the overpayment was found. (See 45 CFR 201.66 for accounting for overpayments.)

PAYMENT DETERMINATION

§ 447.301 Methods and standards for setting reasonable cost-related payment rates.

(a) The plan must set forth the methods and standards used by the agency to set reasonable cost-related payment rates.

(b) The methods and standards must be developed by the agency on the basis of cost-finding methods approved under § 447.276.

(c) The agency must set payment rates on the basis of the methods and standards. The payment rates must be effective no later than January 1, 1978.

§ 447.302 Actual costs.

(a) Methods and standards for determining payment rates must reasonably take into account actual costs of the allowable items set forth in §§ 447.278 through 447.284, reported under § 447.274 and as verfied by audits under §§ 447.292 and 447.293.

(b) Payment rates must not be set lower than rates that the agency reasonably finds to be adequate to reimburse in full the actual allowable costs of a facility that is economically and efficiently operated.

§ 447.303 Economic conditions and trends.

The methods and standards for determining payment rates must reasonably take into account economic conditions and trends during the period for which the rates are set.

§ 447.304 Redetermination of prospective payment rates.

Prospectively determined payment rates must be redetermined at least annually.

§ 447.305 Class rate determination.

If payment rates are determined for a class of facilities, the plan must set forth reasonable criteria for the class and the methods and standards for determining the rate of payment for the class.

§ 447.306 Retroactive downward adjustment provisions.

(a) If facilities are classed by quality of services or level of care and the payment rates provide for adjustment to a prospectively set lower rate for facilities with service deficiencies, the plan must set forth the service deficiencies for which payment may be adjusted to the lower rate.

(b) A ratesetting method that provides for adjustment downward to a prospectively set lower rate is not subject to the upper limits under § 447.316.

§ 447.307 Opportunity for public comment on rates.

(a) Members of the public must have an opportunity to review and comment on proposed rates and the ratesetting methodology before they become effective.

(b) If proposed rates or rate formulas provide for retroactive downward adjustments under § 447.306, the agency, in publishing the proposed rates or rate formulas for public comment, must state the deficiencies under which an adjustment would be made and the amount or percentage rate of the adjustment.

PAYMENT ASSURANCE

§ 447.311 Payment assurance.

The agency must pay amounts determined for long-term care facility services according to the methods and standards set forth in the plan under § 447.301.

UPPER LIMITS: SNF'S, ICF'S

§ 447.315 Upper limits: General provisions.

(a) The agency may not pay more for long-term care facility services than the provider's customary charge.

(b) Public facilities that provide services free or at a nominal charge may be reimbursed on a reasonable cost-related basis under this subpart.

(c) Any limitation on coverage of costs published under §§ 405.460 and 405.461 of this chapter will apply to payments for long-term care facility services.

§ 447.316 Upper limits: Retrospective payment.

(a) If the agency pays a provider under a retrospective payment system, it may not pay more than would be paid under the medicare principles of provider reimbursement under part 405, subpart D, of this chapter. Payments meet this requirement—

(1) If, in a random sample of all medicaid facilities, the payment is not more than the amount that would have been paid under medicare in at least 90 percent of the facilities in the sample; or

(2) If the average payment to all facilities within a class is not more than the amount that would have been paid under medicare.

(b) To determine what would have been paid under medicare—

(1) For facilities that participate in medicare, the interim rate paid to the facility under medicare (adjusted for services not included in the plan) may be used to determine the upper limit; and

(2) For facilities that are not participating in medicare, the agency must

set payment rates that are consistent with the intent that payments do not exceed amounts that would be determined using medicare's principles. In complying with this requirement, the agency need not use medicare's cost reports or methods of cost finding or audit the facilities to use medicare's principles.

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.

The agency may not pay more than the combined payments the provider gets from the beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under medicare.

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Upper limits of payment.

(a) The agency may not pay more for prescribed drugs than the lower of ingredient cost plus a dispensing fee or the provider's usual and customary charge to the general public.

(b) Cost must be determined in accordance with § 447.332.

(c) The dispensing fee must be set by the agency under § 447.333.

§ 447.332 Cost of drugs.

(a) Multiple-source drugs. A "multiple-source drug" means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name. Except as specified in paragraph (b), the cost of each multiple source drug designated by the Pharmaceutical Reimbursement Board (45 CFR Part 19) and published in the FEDERAL REGISTER must be the lower of—

(1) The maximum allowable cost (MAC) established by the Board and published in the FEDERAL REGISTER; or

(2) The estimated acquisition cost as described in paragraph (c) of this section.

(b) *Exception: Certification of brand name drugs.* (1) The cost of a multiple-source drug is not limited to the MAC if a physician certifies in his own handwriting that, in his medical judgment, a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HEW.

(c) *All other drugs.* (1) The agency must set the cost of all other prescribed drugs at the estimated acquisition cost.

(2) "Estimated acquisition cost" means the agency's best estimate of what price providers generally are paying for a drug.

(3) The basis for the estimate must be the package size providers buy most frequently.

NOTE.—To help medicaid agencies with these estimates, HEW makes available information, on a current basis, on the acquisition cost of the most frequently prescribed drugs.

§ 447.333 Dispensing fee.

(a) The agency may set the dispensing fee by taking into account the results of surveys of the costs of pharmacy operation. The agency must periodically survey pharmacy operations including—

(1) Operational data;

(2) Professional services data;

(3) Overhead data; and

(4) Profit data.

(b) The dispensing fee may vary according to—

(1) Size and location of pharmacy;

(2) Whether the drug is a legend item (for which Federal law requires a prescription) or nonlegend item; and

(3) Whether the drug is dispensed by a physician or an outpatient department of an institution.

(c) The dispensing fee may also vary for drugs furnished recipients in institutions by a pharmacy using a unit dose system. In those cases—

(1) The dispensing fee is added to the ingredient cost of the drug actually used; and

(2) The fee is either—

(i) An amount added to the cost of each unit dose; or

(ii) A daily or monthly capitation rate per recipient being furnished drugs.

§ 447.334 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

INDIVIDUAL PRACTITIONERS

§ 447.341 Individual practitioners: Upper limits of payment.

(a) This section applies to doctors of medicine, dentistry, osteopathy, podiatry, and any other individual practitioner services the agency chooses to include.

(b) The agency must not pay the individual practitioner more than the lowest of—

(1) His actual charge for service;

(2) His reasonable charge for the same service under part B, medicare (part 405, subpart D, of this chapter); or

(3) His median charge for a given service.

(c) The median charge for a given service is determined from claims submitted during all of the calendar year preceding the fiscal year in which the determination is made.

(d) The agency must not pay more than the highest of—

(1) The 75th percentile of the range of weighted customary charges in the same locality that are set under medicare during the calendar year preceding the fiscal year in which the determination is made; or

(2) The prevailing reasonable charge under part B, medicare.

OTHER NONINSTITUTIONAL SERVICES

§ 447.351 Selected medical services, supplies and equipment: Upper limits.

(a) Under the medicare criteria for determination of reasonable charges, the Secretary selects and lists in the FEDERAL REGISTER, under § 405.511 of this chapter, medical services, supplies, and equipment (including equipment servicing) that do not generally vary significantly in quality from one supplier to another. Medicare carriers calculate the lowest charge levels at which such services, supplies, and equipment are widely and consistently available within their locality, according to the procedures prescribed in § 405.511.

(b) For those selected services and items furnished under both medicare and medicaid, the agency must not pay more than the lowest charge level calculated by the medicare carrier for the item or service in the locality.

(c) For those selected services and items furnished only under medicaid, the agency must not pay more than the lowest charge levels calculated by the agency under the procedures specified in § 405.511 (c) and (d) of this chapter.

§ 447.352 Other noninstitutional services: Upper limits.

(a) For any noninstitutional item or service furnished under both medicare and medicaid and not subject to the

upper limits specified in § 447.351 or other sections of this part, the agency must not pay more than the reasonable charge established for that item or service by a medicare carrier serving part or all of the State.

(b) For all other noninstitutional items or services furnished only under medicaid and not subject to the upper limits specified in § 447.351 or other sections of this part, the agency must not pay more than the customary charge for a provider or the prevailing charge in the locality for comparable items or services under comparable circumstances, whichever is lower. For this purpose, the agency must set prevailing charges on the basis of the combined payments that providers receive from other third party insurers and their subscribers and policyholders.

PREPAID CAPITATION PLANS

§ 447.361 Prepaid capitation plans: Upper limits of payment.

The agency must not pay more for a defined scope of services to a defined number of recipients under a capitation arrangement than the cost of providing those same services on a fee-for-service basis, and must not pay more than other third party payors are paying for comparable services under comparable circumstances.

RURAL HEALTH CLINIC SERVICES

§ 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in § 440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in § 440.20(c) of this subchapter, as follows:

(a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in subpart D of part 405 of this chapter. For purposes of this section, a provider clinic is an integral part of a hospital, skilled nursing facility, or home health agency that is participating in medicare and is licensed, governed, and supervised with other departments of the facility.

(b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined by a medicare carrier under §§ 405.2426 through 405.2429 of this chapter.

(c) For clinics other than provider clinics that do offer ambulatory services other than rural health clinic services, the agency must pay for the other ambulatory services by one of the following methods:

(1) The agency may pay for other ambulatory services and rural health clinic services at a single rate per visit that is based on the cost of all services furnished by the clinic. The rate must be determined by a medicare carrier under §§ 405.2526 through 405.2429 of this chapter.

(2) The agency may pay for other ambulatory services at a rate set for each service by the agency. The rate must not exceed the upper limits in this subpart. The agency must pay for rural health clinic services at the medicare reimbursement rate per visit, as specified in § 405.2426 of this chapter.

(3) The agency may pay for dental services at a rate per visit that is based on the cost of dental services furnished by the clinic. The rate must be determined by a medicare carrier under §§ 405.2426 through 405.2429 of this chapter. The agency must pay for ambulatory services other than dental services under paragraph (c) (1) or (2) of this section.

(d) For purposes of paragraph (c) (1) and (3) of this section, "visit" means a face-to-face encounter between a clinic patient and any health professional whose services are reimbursed under the State plan. Encounters with more than one health professional, and multiple encounters with the same health professional, that take place on the same day and at a single location constitute a single visit, except when the patient, after the first encounter, suffers illness or injury requiring additional diagnosis or treatment.

PART 455—PROGRAM INTEGRITY

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

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Subpart B—Disclosure of Information by Providers and Fiscal Agents

455.104 Disclosure by intermediate care facilities of ownership and control information.

Subpart D—State Medicaid Fraud Control Units

455.300 State medicaid fraud control units.

AUTHORITY: Sec. 1102 Social Security Act, 49 Stat. 647 (42 U.S.C. 1302).

Subpart A—Medicaid Agency Fraud Detection and Investigation Program

§ 455.10 Basis and purpose.

This subpart—

(a) Prescribes requirements, based on section 1902(a)(4) of the Act, for medicaid agency prevention and control of program fraud and abuse;

(b) Requires agencies to inform providers and recipients of the Federal penalties for fraud under section 1909 of the Act; and

(c) Implements section 1903(i)(2) of the Act, prohibiting FFP for payments to Medicaid providers who are ineligible for payments under medicare because of a determination by the Secretary relating to false or excessive claims.

§ 455.11 Definition of fraud.

For purposes of this subpart the definition of fraud is determined according to State law.

§ 455.12 State plan requirement.

A State plan must meet the requirements of §§ 455.13-455.22.

§ 455.13 Methods for identification, investigation and referral.

The medicaid agency must have—

(a) Methods and criteria for identifying suspected fraud cases;

(b) Methods for investigating these cases that—

(1) Do not infringe on the legal rights of persons involved; and

(2) Afford due process of law; and

(c) Procedures, developed in cooperation with State legal authorities, for referring suspected fraud cases to law enforcement officials. The procedures must include designating an agency position with responsibility for making referrals.

§ 455.14 Preliminary investigation.

If the agency receives a complaint of fraud or abuse from any source, it must conduct a preliminary investigation to determine whether there is sufficient merit to warrant the initiation of a full investigation.

§ 455.15 Full investigation.

If the findings of a preliminary investigation give the agency reason to believe the allegation, the agency must conduct a full investigation to determine if—

(a) The allegation is true; and

(b) There is sufficient evidence that can be developed to support a civil or criminal fraud or abuse action under State law.

§ 455.16 **Resolution of full investigation.**

A full investigation must continue until—

(a) Appropriate legal action is initiated;

(b) The case is closed or dropped because of insufficient evidence to support the allegations of fraud or abuse; or

(c) The matter is resolved between the agency and the provider. This resolution may include but is not limited to—

(1) Sending a warning letter to the provider giving notice that continuation of the activity in question will result in further action;

(2) Suspending the provider from participation in the medicaid program;

(3) Terminating the provider from participation in the medicaid program; or

(4) Seeking recovery of payments made to the provider.

§ 455.17 **Reporting to HCFA.**

The agency must report the following fraud and abuse information to the Regional HCFA Administrator at intervals prescribed in HCFA instructions:

(a) The number of complaints of fraud and abuse made to the agency that warrant preliminary investigation.

(b) For each case of suspected fraud and abuse that warrants a full investigation—

(1) The provider's name and number;

(2) The source of the complaint;

(3) The type of provider;

(4) The nature of the complaint;

(5) The approximate range of dollars involved; and

(6) The legal and administrative disposition of the case, including actions taken by law enforcement officials to whom the case has been referred.

(c) A summary of the information reported in paragraph (b) of this section.

§ 455.18 **Provider's statements on claims form.**

(a) Except as provided in § 455.19, the agency must provide that all provider claims forms be imprinted in boldface type with the following statements, or with alternate wording that is approved by the Regional HCFA Administrator:

(1) "This is to certify that the foregoing information is true, accurate, and complete."

(2) "I understand that payment of this claim will be from Federal and State funds, and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."

(b) The statements may be printed above the claimant's signature or, if they are printed on the reverse of the form, a reference to the statements must appear immediately preceding the claimant's signature.

§ 455.19 **Provider's statement on check.**

As an alternative to the statements required in § 455.18, the agency may print the following wording above the claimant's endorsement on the reverse of checks or warrants payable to each provider: "I understand in endorsing or depositing this check that payment will be from Federal and State funds and that any falsification, or concealment of a material fact, may be prosecuted under Federal and State laws."

§ 455.20 **Recipient verification procedure.**

(a) The agency must have a method for verifying with recipients whether services billed by providers were received.

(b) In States receiving Federal matching funds for a mechanized claims processing and information retrieval system under part 433, subpart C, of this subchapter, the agency must provide prompt written notice as required by § 433.113(b)(2) to—

(1) Each recipient for whom services were billed; or

(2) Each recipient in a sample group of recipients for whom services were billed.

(c) In States not receiving Federal matching funds for a mechanized system, verification may be made by:

(1) A random sample of recipients for each provider who is paid significant amounts (i.e., high-volume providers); and

(2) A random sample of recipients for groups of providers who are not paid significant amounts (i.e., low-volume providers).

§ 455.21 **Cooperation with State medicaid fraud control units.**

In a State with a medicaid fraud control unit established and certified under subpart F of this part:

(a) The agency must—

(1) Refer all cases of suspected provider fraud to the unit;

(2) If the unit determines that it may be useful in carrying out the unit's responsibilities, promptly comply with a request from the unit for—

(i) Access to, and free copies of, any records or information kept by the agency or its contractors;

(ii) Computerized data stored by the agency or its contractors. This data must be supplied without charge and in the form requested by the unit; and

(iii) Access to any information kept by providers to which the agency is authorized access by sec. 1902(a)(27) of the Act and § 431.107 of this subchapter. In using this information, the unit must protect the privacy rights of recipients; and

(3) On referral from the unit, initiate any available administrative or judicial action to recover improper payments to a provider.

(b) The agency need not comply with specific requirements under this subpart that are the same as the responsibilities placed on the unit under subpart F of this part.

§ 455.22 **Notification of penalties.**

The agency must notify providers and recipients of the provisions of sec. 1909 of the Act that provide Federal penalties for fraudulent acts and false reporting.

§ 455.23 **Denial of FFP.**

No FFP is available in payments for services by a provider or other person who is ineligible to receive payment under medicare because of a determination under § 405.315a or § 405.614 of this chapter relating to false or excessive claims. Suspension of FFP is effective when the Administrator notifies the agency of the determination, and continues for the period of ineligibility under medicare.

Subpart B—Disclosure of Information by Providers and Fiscal Agents

§ 455.104 **Disclosure by intermediate care facilities of ownership and control information.**

(a) A State plan must provide that an intermediate care facility receiving medicaid payments must submit to the State licensing agency the information specified in this section and must promptly report any changes in it.

(b) The facility must submit complete information on the identity of—

(1) Each individual who has, directly or indirectly, an ownership interest of 5 percent or more in the facility;

(2) Each individual who owns, in whole or in part, any mortgage, deed of trust, note or other obligation secured, in whole or in part, by the facility or by any property or asset of the facility;

(3) Each corporation officer or director, if the facility is a corporation; and

(4) Each partner, if the facility is a partnership.

Subpart D—State Medicaid Fraud Control Units

§ 455.300 **State medicaid fraud control units.**

(a) *Definitions.* As used in this section, unless otherwise indicated by the context:

"Employ" or "employee", as the context requires, means full-time duty intended to last at least a year. It includes an arrangement whereby an individual is on full-time detail or assign-

ment to the unit from another government agency, if the detail or assignment is for a period of at least 1 year and involves supervision by the unit.

"Provider" means an individual or entity which furnishes items or services for which payment is claimed under medicaid.

"Unit" means the State medicaid fraud control unit.

(b) *Scope and purpose.* This section implements section 1903(a)(6), 1903(b)(3), and 1903(q) of the Social Security Act, as amended by the Medicare-Medicaid Anti-Fraud and Abuse Amendments (Pub. L. 95-142 of October 25, 1977). The statute authorizes the Secretary to pay a State 90 percent of the costs of establishing and operating a State medicaid fraud control unit, as defined by the statute, for the purpose of eliminating fraud in the State medicaid program.

(c) *Basic requirement.* A State medicaid fraud control unit must be a single identifiable entity of the State government certified by the Secretary as meeting the requirements of paragraphs (d) through (g) of this section.

(d) *Organization and location requirements.* Any of the following three alternatives is acceptable:

(1) The unit is located in the office of the State attorney general or another department of State government which has statewide authority to prosecute individuals for violations of criminal laws with respect to fraud in the provision or administration of medical assistance under a State plan implementing title XIX of the Act; or

(2) If there is no State agency with statewide authority and capability for criminal fraud prosecutions, the unit has established formal procedures which assure that the unit refers suspected cases of criminal fraud in the State medicaid program to the appropriate State prosecuting authority or authorities, and provides assistance and coordination to such authority or authorities in the prosecution of such cases; or

(3) The unit has a formal working relationship with the office of the State attorney general and has formal procedures for referring to the attorney general suspected criminal violations occurring in the State medicaid program and for effective coordination of the activities of both entities relating to the detection, investigation and prosecution of those violations. Under this requirement, the office of the State attorney general must agree to assume responsibility for prosecuting alleged criminal violations referred to it by the unit. However, if the attorney general finds that another prosecuting authority has the demonstrated capacity, experience and willingness to prosecute an alleged violation, he may refer a case to that prosecuting authority, as long as his office maintains oversight responsibility for the prosecution and for coordination between the unit and the prosecuting authority.

(e) *Relationship to, and agreement with, the medicaid agency.* (1) The unit must be separate and distinct from the medicaid agency.

(2) No official of the medicaid agency shall have authority to review the activities of the unit or to review or overrule the referral of a suspected criminal violation to an appropriate prosecuting authority.

(3) The unit shall not receive funds paid under this section either from or through the medicaid agency.

(4) The unit shall enter into an agreement with the medicaid agency under which the medicaid agency will agree to comply with all requirements of § 455.21(a)(2).

(f) *Duties and responsibilities of the unit.* (1) The unit shall conduct a statewide program for investigating and prosecuting (or referring for prosecution) violations of all applicable State laws pertaining to fraud in the administration of the medicaid program, the provision of medical assistance, or the activities of providers of medical assistance under the State medicaid plan.

(2) The unit shall also review complaints alleging abuse or neglect of patients in health care facilities receiving payments under the State medicaid plan and may review complaints of the misappropriation of patient's private funds in such facilities.

(i) If the initial review indicates substantial potential for criminal prosecution, the unit shall investigate the complaint or refer it to an appropriate criminal investigative or prosecutive authority.

(ii) If the initial review does not indicate a substantial potential for criminal prosecution, the unit shall refer the complaint to an appropriate State agency.

(3) If the unit, in carrying out its duties and responsibilities under paragraphs (f) (1) and (2) of this section, discovers that overpayments have been made to a health care facility or other provider of medical assistance under the State medicaid plan, the unit shall either attempt to collect such overpayment or refer the matter to an appropriate State agency for collection.

(4) Where a prosecuting authority other than the unit is to assume responsibility for the prosecution of a case investigated by the unit, the unit shall insure that those responsible for the prosecutive decision and the preparation of the case for trial have the fullest possible opportunity to participate in the investigation from its inception and will provide all necessary assistance to the prosecuting authority throughout all resulting prosecutions.

(5) The unit shall make available to Federal investigators or prosecutors all information in its possession concerning fraud in the provision or administration of medical assistance under the State plan and shall cooperate with such officials in coordinating any Federal and State investigations or prosecutions involving the same suspects or allegations.

(6) The unit shall safeguard the privacy rights of all individuals and shall provide safeguards to prevent the misuse of information under the unit's control.

(g) *Staffing requirements.* (1) The unit shall employ sufficient professional, administrative, and support staff to carry out its duties and responsibilities in an effective and efficent manner. The staff must include:

(i) One or more attorneys experienced in the investigation or prosecution of civil fraud or criminal cases, who are capable of giving informed advice on applicable law and procedures and providing effective prosecution or liaison with other prosecutors;

(ii) One or more experienced auditors capable of supervising the review of financial records and advising or assisting in the investigation of alleged fraud;

(iii) A senior investigator with substantial experience in commercial or financial investigations who is capable of supervising and directing the investigative activities of the unit.

(2) The unit shall employ, or have available to it, professional staff who are knowledgeable about the provision of medical assistance under title XIX and about the operation of health care providers.

(h) *Applications, certification, and recertification.*—(1) *Initial application.* In order to receive FFP under this section, the unit must submit to the Secretary, an application approved by the Governor, containing the following information and documentation.

(i) A description of the applicant's organization, structure, and location within State government, and an indication of whether it seeks certification under paragraph (d)(1), (d)(2), or (d)(3) of this section;

(ii) A statement from the State attorney general that the applicant has authority to carry out the functions and responsibilities set forth in this section. If the applicant seeks certification under paragraph (d)(2) of this section, the statement must also specify either that there is no State agency with the authority to exercise statewide prosecuting authority for the violations with which the unit is concerned, or that, although the State

attorney general may have common law authority for statewide criminal prosecutions, he has not exercised that authority.

(iii) A copy of whatever memorandum of agreement, regulation, or other document sets forth the formal procedures required under paragraph (d)(2) of this section or the formal working relationship and procedures required under paragraph (d)(3) of this section;

(iv) A copy of the agreement with the medicaid agency required under paragraph (e) of this section;

(v) A statement of the procedures to be followed in carrying out the functions and responsibilities of this section;

(vi) A projection of the caseload and a proposed budget for the 12-month period for which certification is sought; and

(vii) Current and projected staffing, including the names, education, and experience of all senior professional staff already employed and job descriptions, with minimum qualifications, for all professional positions.

(2) *Conditions for, and notification of certification.* (i) The Secretary will approve an application only if he has specifically approved the applicant's formal procedures under paragraph (d)(2) or (d)(3) of this section, if either of those provisions is applicable, and has specifically certified that the applicant meets the requirements of paragraph (d) of this section.

(ii) The Secretary will promptly notify the applicant whether the application meets the requirements of this section and is approved. If the application is not approved, the applicant may submit an amended application at any time. Approval and certification will be for a period of 1 year.

(3) *Conditions for recertification.* In order to continue receiving payments under this section, a unit must submit a reapplication to the Secretary at least 60 days prior to the expiration of the 12-month certification period. A reapplication must:

(i) Advise the Secretary of any changes in the information or documentation required under paragraph (h)(1) (i) through (v) of this section.

(ii) Provide projected caseload and proposed budget for the recertification period; and

(iii) Include or incorporate by reference the annual report required under paragraph (i) of this section.

(4) *Basis for recertification.* (i) The Secretary will consider the unit's reapplication, the reports required under paragraph (i) of this section, and any other reviews or information he deems necessary or warranted, and will promptly notify the unit whether he has approved the reapplication and recertified the unit.

(ii) In reviewing the reapplication, the Secretary will give special attention to whether the unit has used its resources effectively in investigating cases of possible fraud, in preparing cases for prosecution, and in prosecuting cases or cooperating with the prosecuting authorities.

(i) *Reporting requirements.*—(1) *Annual report.* At least 60 days prior to the expiration of the certification period, the unit shall submit to the Secretary a report covering the last 12 months (the first 9 months of the certification period for the first annual report), and containing the following information:

(i) The number of investigations initiated and the number completed or closed, categorized by type of provider;

(ii) The number of cases prosecuted or referred for prosecution; the number of cases finally resolved and their outcomes; and the number of cases investigated but not prosecuted or referred for prosecution because of insufficient evidence;

(iii) The number of complaints received regarding abuse and neglect of patients in health care facilities; the number of such complaints investigated by the unit; and the number referred to other identified State agencies.

(iv) The number of recovery actions initiated by the unit; the number of recovery actions referred to another agency; the total amount of overpayments identified by the unit; and the total amount of overpayments actually collected by the unit;

(v) The number of recovery actions initiated by the medicaid agency under its agreement with the unit; and the total amount of overpayments actually collected by the medicaid agency under this agreement;

(vi) Projections for the succeeding 12 months for items listed in paragraphs (i)(1) (i) through (v) of this section;

(vii) The costs incurred by the unit, by major budget category; and

(viii) A narrative that evaluates the unit's performance; describes any specific problems it has had in connection with the procedures and agreements required under this section; and discusses any other matters that have impaired its effectiveness.

(2) The unit shall also provide any additional reports that the Secretary requests, and shall comply with any measures the Secretary deems necessary to assure the accuracy and completeness of all reports required under this paragraph (i).

(j) *Federal financial participation (FFP).*—(1) *Rate of FFP.* Subject to the limitations specified in this paragraph, the Secretary will reimburse each certified State medicaid fraud control unit, by an amount equal to 90 percent of the costs incurred by that unit which are attributable to carrying out its functions and responsibilities under this section. The costs subject to reimbursement will be determined under 45 CFR part 74, except as provided otherwise in this part or in the grant award.

(2) *Basis and period of payment.* (i) Payment will be made for each quarter, based on quarterly reports submitted by the unit in the format and containing the information requested by the Secretary.

(ii) Payments are available for each quarter during fiscal years 1978, 1979, and 1980.

(iii) The Secretary may grant certification retroactive to the date on which the unit first met all the requirements of the statute and of this section. For any quarter with respect to which the unit is certified, the Secretary will provide reimbursement for the entire quarter.

(3) *Amount of FFP.* The amount paid during any quarter shall not exceed the higher of $125,000 or one-quarter of 1 percent of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State medicaid program.

(4) *Costs subject to FFP.* FFP is available under this section for the expenditures attributable to the establishment and operation of the unit, including the cost of training personnel employed by the unit. Reimbursement shall be limited to costs attributable to the specific responsibilities and functions set forth in this section in connection with the investigation and prosecution of suspected fraudulent activities and the review of complaints of alleged abuse or neglect of patients in health care facilities. Establishment costs are limited to clearly identifiable costs of personnel that:

(i) Devote full time to the establishment of the unit which does achieve certification; and

(ii) Continue as full-time employees after the unit is certified.

All establishment costs will be deemed made in the first quarter of certification.

(5) *Costs not subject to FFP.* FFP is not available under this section for expenditures attributable to:

(i) The investigation of cases involving program abuse or other failures to comply with applicable laws and regulations, if these cases do not involve substantial allegations or other indications of fraud;

(ii) Efforts to identify situations in which a question of fraud may exist, including the screening of claims, analysis of patterns of practice, or routine verification with recipients of whether services billed by providers were actually received;

(iii) The routine notification of providers that fraudulent claims may be punished under Federal or State law;

(iv) The performance by a person other than a full-time employee of the unit of any management function for the unit, any audit or investigation, any professional legal function, or any criminal, civil or administrative prosecution of suspected providers;

(v) The investigation or prosecution of cases of suspected recipient fraud not involving suspected conspiracy with a provider; or

(vi) Any payment, direct or indirect, from the unit to the medicaid agency, other than payments for the salaries of employees on detail to the unit.

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Subpart A—General Provisions

§ 456.1 Basis and purpose of part.

(a) This part prescribes requirements concerning control of the utilization of medicaid services including—

(1) A statewide program of control of the utilization of all medicaid services; and

(2) Specific requirements for the control of the utilization of medicaid services in institutions.

(b) The requirements in this part are based on the following sections of the Act. Table 1 shows the relationship between these sections of the Act and the requirements in this part.

(1) *Methods and procedures to safeguard against unnecessary utilization of care and services.* Section 1902(a)(30) requires that the State plan provide methods and procedures to safeguard against unnecessary utilization of care and services.

(2) *Penalty for failure to have an effective program to control utilization of institutional services.* Section 1903(g)(1) provides for a reduction in the amount of Federal medicaid funds paid to a State for long-stay inpatient services if the State does not make a showing satisfactory to the Secretary that it has an effective program of control over utilization of those services. This penalty provision applies to inpatient services in hospitals, mental hospitals, skilled nursing facilities (SNF's), and intermediate care facilities (ICF's). Specific requirements are:

(i) Under sec. 1903(g)(1)(A), a physician must certify at admission, and periodically recertify, the individual's need for inpatient care.

(ii) Under sec. 1903(g)(1)(B), services must be furnished under a plan established and periodically evaluated by a physician.

(iii) Under sec. 1903(g)(1)(C), the State must have in effect a continuous program of review of utilization of care and services under section 1902(a)(30) whereby each admission is reviewed or screened in accordance with criteria established by medical and other professional personnel.

(iv) Under sec. 1903(g)(1)(D), the State must have an effective program under sections 1902(a) (26) and (31) of review of care in skilled nursing and intermediate care facilities and mental hospitals. This must include evaluation at least annually of the professional management of each case.

(3) *Medical review in skilled nursing facilities and mental hospitals.* Section 1902(a)(26)(A) requires that the plan provide for a program of medical review that includes a medical evaluation of each individual's need for care in a SNF or mental hospital, a plan of care, and, where applicable, a plan of rehabilitation.

(4) *Independent professional review in intermediate care facilities.* Section 1902(a)(31)(A) requires that the plan provide for a program of independent professional review that includes a medical evaluation of each individual's need for intermediate care and a written plan of service.

(5) *Inspection of care and services in institutions.* Sections 1902(a)(26) (B) and (C) and 1902(a)(31) (B) and (C) require that the plan provide for periodic inspections and reports, by a team of professional persons, of the care being provided to each recipient in SNF's, institutions for mental diseases (IMD's), and ICF's participating in medicaid.

(6) *Denial of FFP for failure to have specified utilization review procedures.* Section 1903(i)(4) provides that FFP is not available in a State's expenditures for hospital, mental hospital, or SNF services unless the institution has in effect a utilization review plan that meets medicare requirements. However, the Secretary may waive this requirement if the medicaid

agency demonstrates to his satisfaction that it has utilization review procedures superior in effectiveness to the medicare procedures.

(7) *State health agency guidance on quality and appropriateness of care and services.* Section 1902(a)(33)(A) requires that the plan provide that the State health or other appropriate medical agency establish a plan for review, by professional health personnel, of the appropriateness and quality of medicaid services to provide guidance to the medicaid agency and the State licensing agency in administering the medicaid program.

TABLE 1

This table relates the regulations in this part to the sections of the Act on which they are based.

Subpart A—General	1902(a)(30) 1902(a)(33)(A)
Subpart B—Utilization Control: All Medicaid Services	1902(a)(30)
Subpart C—Utilization Control: Hospitals	
Certification of need for care	1903(g)(1)(A)
Plan of care	1903(g)(1)(B)
Utilization review plan (including admission review)	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart D—Utilization Control: Mental Hospitals	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Admission and plan of care requirements for individuals under 21	1902(a)(26)(A) 1903(g)(1) (B), (C)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart E—Utilization Control: Skilled Nursing Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review	1902(a)(26)(A) 1903(g)(1)(C)
Plan of care	1902(a)(26)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Discharge plan	1902(a)(30)
Subpart F—Utilization Control: Intermediate Care Facilities	
Certification of need for care	1903(g)(1)(A)
Medical evaluation and admission review	1902(a)(31)(A) 1903(g)(1)(C)
Plan of care	1902(a)(31)(A) 1903(g)(1)(B)
Utilization review plan	1902(a)(30) 1903(g)(1)(C) 1903(i)(4)
Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements	1905 (a)(16) and (h)
Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals, Mental Hospitals and Skilled Nursing Facilities	1902(a)(30), 1903(i)(4)
Subpart I—Inspections of Care in Skilled Nursing and Intermediate Care Facilities and Institutions for Mental Diseases	1902(a) (26) (B), (C), (31) (B), (C) 1903(g)(1)(D)

TABLE 1—Continued

§ 456.2 State plan requirements.

A State plan must provide that the requirements of this part are met.

§ 456.3 Statewide surveillance and utilization control program.

The medicaid agency must implement a statewide surveillance and utilization control program that—

(a) Safeguards against unnecessary or inappropriate use of medicaid services and against excess payments;

(b) Assesses the quality of those services;

(c) Provides for the control of the utilization of all services provided under the plan in accordance with subpart B of this part; and

(d) Provides for the control of the utilization of inpatient services in accordance with subparts C through I of this part.

§ 456.4 Responsibility for monitoring the utilization control program.

(a) The agency must—

(1) Monitor the statewide utilization control program;

(2) Take all necessary corrective action to ensure the effectiveness of the program;

(3) Establish methods and procedures to implement this section;

(4) Keep copies of these methods and procedures on file; and

(5) Give copies of these methods and procedures to all staff involved in carrying out the utilization control program.

§ 456.5 Evaluation criteria.

The agency must establish and use written criteria for evaluating the appropriateness and quality of medicaid services. This section does not apply to services in hospitals, mental hospitals, and SNF's. For these facilities, see the following sections: §§ 456.122 and 456.132 of subpart C; § 456.232 of subpart D; and § 456.332 of subpart E.

§ 456.6 Review by State medical agency of appropriateness and quality of services.

(a) The medicaid agency must have an agreement with the State health agency or other appropriate State medical agency, under which the health or medical agency is responsible for establishing a plan for the review by professional health personnel of the appropriateness and quality of medicaid services.

(b) The purpose of this review plan is to provide guidance to the medicaid agency in the administration of the State plan and, where applicable, to the State licensing agency described in § 431.610.

Subpart B—Utilization Control: All Medicaid Services

§ 456.21 Scope.

This subpart prescribes utilization control requirements applicable to all services provided under a State plan.

§ 456.22 Sample basis evaluation of services.

To promote the most effective and appropriate use of available services and facilities the medicaid agency must have procedures for the on-going evaluation, on a sample basis, of the need for and the quality and timeliness of medicaid services.

§ 456.23 Post-payment review process.

The agency must have a post-payment review process that—

(a) Allows State personnel to develop and review—

(1) Recipient utilization profiles;

(2) Provider service profiles; and

(3) Exceptions criteria; and

(b) Identifies exceptions so that the agency can correct misutilization practices of recipients and providers.

Subpart C—Utilization Control: Hospitals

§ 456.50

Scope.

This subpart prescribes requirements for control of utilization of inpatient hospital services, including requirements concerning—

(a) Certification of need for care;

(b) Plan of care; and

(c) Utilization review plans.

§ 456.51 Definitions.

As used in this subpart:

"Inpatient hospital services"—

(a) Include—

(1) Services provided in an institution other than an institution for tuberculosis or mental disease, as defined in § 440.10;

(2) Services provided in an institution for tuberculosis, as defined in § 440.140; and

(3) Services provided in specialty hospitals and

(b) Exclude services provided in mental hospitals. Utilization control requirements for mental hospitals appear in subpart D.

"Medical care appraisal norms" or "norms" means numerical or statisti-

cal measures of usually observed performance.

"Medical care criteria" or "criteria" means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.60 Physician certification and recertification of need for inpatient care.

(a) A physician must certify and recertify for each applicant or recipient that inpatient services in a hospital are or were needed.

(b) The certification must be made at the time of admission or, if an individual applies for assistance while in a hospital, before the medicaid agency authorizes payment.

(c) Recertifications must be made at least every 60 days after certification.

PLAN OF CARE

§ 456.80 Individual written plan of care.

(a) Before admission to a hospital or before authorization for payment, a physician and other personnel involved in the care of the individual must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Social services;

(vi) Diet;

(4) Plans for continuing care, as appropriate; and

(5) Plans for discharge, as appropriate.

(c) Orders and activities must be developed in accordance with physician's instructions.

(d) Orders and activities must be reviewed and revised as appropriate by all personnel involved in the care of an individual.

(e) A physician and other personnel involved in the recipient's case must review each plan of care at least every 60 days.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.100 Scope.

Sections 456.101 through 456.145 of this subpart prescribe requirements for a written utilization review (UR) plan for each hospital providing medicaid services. Sections 456.105 and 456.106 prescribe administrative requirements: §§ 456.111 through 456.113 prescribe informational requirements; §§ 456.121 through 456.129 prescribe requirements for admission review; §§ 456.131 through 456.137 prescribe requirements for continued stay review; and §§ 456.141 through 456.145 prescribe requirements for medical care evaluation studies.

§ 456.101 UR plan required for inpatient hospital services.

(a) A State plan must provide that each hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the hospital furnishes him.

(b) Each written hospital UR plan must meet the requirements under §§ 456.101 through 456.145.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.105 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.106 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the hospital staff;

(2) A group outside the hospital staff, established by the local medical or osteopathic society and at least some of the hospitals and SNF's in the locality;

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of the patient whose care is being reviewed; or

(2) Has a financial interest in any hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.111 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed for the UR committee to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.70.

(e) Initial and subsequent continued stay review dates described under § 456.128 and § 456.133.

(f) Date of operating room reservation, if applicable.

(g) Justification of emergency admission, if applicable.

(h) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(i) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.112 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.113 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR ADMISSION [1]

§ 456.121 Admission review required.

The UR plan must provide for a review of each recipient's admission to the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.122 through 456.129.

§ 456.122 Evaluation criteria for admission review.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for admission; and

[1] The Department was enjoined in 1975 in the case of American Medical Assn. et al. v. Weinberger, 395 F. Supp. 515 (N.D. Ill., 1975), aff'd., 522 F2d 921 (7th cir., 1975) from implementing the admission review requirements contained in §§ 456.121-456.127. This case was dismissed on the condition that these requirements be revised. They are presently being revised, and will not be in force until that revision is completed.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.123 Admission review process.

The UR plan must provide that—

(a) Admission review is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup, or designee evaluates the admission against the criteria developed under § 456.122 and applies close professional scrutiny to cases selected under § 456.129(b);

(c) If the committee, subgroup, or designee finds that the admission is needed, the committee assigns an initial continued stay review date in accordance with § 456.128;

(d) If the committee, subgroup, or designee finds that the admission does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for admission;

(e) If the committee or subgroup making the review under paragraph (d) of this section finds that the admission is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(f) If the attending physician does not present additional information or clarification of the need for the admission, the decision of the committee or subgroup is final; and

(g) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the admission. If they find that the admission is not needed, their decision if final.

§ 456.124 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for admission under § 456.123 (e) through (g) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.125 Time limits for admission review.

Except as required under § 456.127, the UR plan must provide that review of each recipient's admission to the hospital is conducted—

(a) Within one working day after admission, for an individual who is receiving medicaid at that time; or

(b) Within one working day after the hospital is notified of the application for medicaid, for an individual who applies while in the hospital.

§ 456.126 Time limits for final decision and notification of adverse decision.

Except as required under § 456.127, the UR plan must provide that the committee makes a final decision on a recipient's need for admission and gives notice of an adverse final decision—

(a) Within two working days after admission, for an individual who is receiving medicaid at that time; or

(b) Within two working days after the hospital is notified of the application for medicaid, for an individual who applies while in the hospital.

§ 456.127 Pre-admission review.

The UR plan must provide for review and final decision prior to admission for certain providers or categories of admissions that the UR committee designates under § 456.142(b)(4)(iii) to receive pre-admission review.

§ 456.128 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the hospital under the admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.129;

(2) The individual's condition; and

(3) The individual's projected discharge date;

(c)(1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These regional norms are based on current and statistically valid data on duration of stay in hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose case is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate; and

(d) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.129 Description of methods and criteria: Initial continued stay review date; close professional scrutiny; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee uses to assign the initial continued stay review date under § 456.128.

(b) The methods that the committee uses to select categories of admission to receive close professional scrutiny under § 456.123(b); and

(c) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

UR Plan: Review of Need for Continued Stay

§ 456.131 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the hospital to decide whether it is needed, in accordance with the requirements of §§ 456.132 through 456.137.

§ 456.132 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.133 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.128 and 456.134(a);

(b) The committee assigns a subsequent review date each time it decides under § 456.135 that the continued stay is needed; and

(c) The committee ensures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.134 Description of methods and criteria: Subsequent continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the committee

uses to assign subsequent continued stay review dates under § 456.133; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.135 Continued stay review process.

The UR plan must porovide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.111 against the criteria developed under § 456.132 and applies close professional scrutiny to cases selected under § 456.129(b);

(d) if the committee, subgroup, or designee finds that a recipient's continued stay in the hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.133;

(e) If the committee, subgroup, or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his reviews before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee or subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. If they find that the recipient no longer needs inpatient hospital services, their decision is final.

§ 456.136 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.135 (f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending physician;

(c) The medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.137 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.136 of an adverse final decision within 2 working days after the assigned continued stay review dates, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.136 within 2 working days after the date of the final decision.

UR Plan: Medical Care Evaluation Studies

§ 456.141 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.142 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process for admissions or continued stay cases;

(ii) Recommend more effective and efficient hospital care procedures; or

(iii) Designate certain providers or categories of admissions for review prior to admission.

§ 456.143 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Indentify and analyze medical or administrative factors related to the hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions;

(2) Durations of stay;

(3) Ancillary services furnished, including drugs and biologicals;

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for changes beneficial to patients, staff, the hospital, and the community.

§ 456.144 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data;

(b) External organizations that compile statistics, design profiles, and produce other comparative data;

(c) Cooperative endeavors with—

(1) PSRO's;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

§ 456.145 Number of studies required to be performed.

The hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart D—Utilization Control: Mental Hospitals

§ 456.150 Scope.

This subpart prescribes requirements for control of utilization of inpatient services in mental hospitals, including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.151 Definitions.

As used in this subpart:

"Medical care appraisal norms" or "norms" means numerical or statistical measures of usually observed performance.

"Medical care criteria" or "criteria" means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

CERTIFICATION OF NEED FOR CARE

§ 456.160 Physician certification and recertification of need for inpatient care.

(a) A physician must certify and recertify for each applicant or recipient that inpatient services in a mental hospital are or were needed.

(b) The certification must be made at the time of admission or, if an individual applies for assistance while in a mental hospital, before the Medicaid agency authorizes payment.

(c) Recertifications must be made at least every 60 days after certification.

MEDICAL, PSYCHIATRIC, AND SOCIAL EVALUATIONS AND ADMISSION REVIEW

§ 456.170 Medical, psychiatric, and social evaluations.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must make a medical evaluation of each applicant's or recipient's need for care in the hospital; and appropriate professional personnel must make a psychiatric and social evaluation.

(b) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the mental hospital; or

(ii) Continued care in the mental hospital for individuals who apply for Medicaid while in the mental hospital.

§ 456.171 Medicaid agency review of need for admission.

Medical and other professional personnel of the medicaid agency or its designess must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.170.

PLAN OF CARE

§ 456.180 Individual written plan of care.

(a) Before admission to a mental hospital or before authorization for payment, the attending physician or staff physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 90 days.

§ 456.181 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the facility, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENTS

§ 456.200 Scope.

Sections 456.201 through 456.245 of this subpart prescribe requirements for a written utilization review (UR) plan for each mental hospital providing medicaid services. Sections 456.205 and 456.206 prescribe administrative requirements; §§ 456.211 through 456.213 prescribe informational requirements; §§ 456.231 through 456.238 prescribe requirements for continued stay review; and §§ 456.241 through 456.245 prescribe requirements for medical care evaluation studies.

§ 456.201 UR plan required for inpatient mental hospital services.

(a) The State plan must provide that each mental hospital furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the mental hospital furnishes him.

(b) Each written mental hospital UR plan must meet the requirements under §§ 456.201 through 456.245.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.205 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.206 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians, one of whom is knowledgeable in the diagnosis and treatment of mental diseases, and assisted by other professional personnel.

(c) The UR committee must be constituted as—

(1) A committee of the mental hospital staff;

(2) A group outside the mental hospital staff, established by the local medical or osteopathic society and at least some of the hospital and SNF's in the locality; or

(3) A group capable of performing utilization review, established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed; or

(2) Has a financial interest in any mental hospital.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.211 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission, and dates of application for and authorization of medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.172.

(e) Initial and subsequent continued stay review dates described under §§ 456.233 and 456.234.

(f) Reasons and plan for continued stay, if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.212 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports and arrangements for their distribution to appropriate individuals.

§ 456.213 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.231 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the mental hospital to decide whether it is needed, in accordance with the requirements of §§ 456.232 through 456.238.

§ 456.232 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay.

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.233 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the mental hospital under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for medicaid while in the mental hospital, the committee assigns the initial continued stay review date within 1 working day after the mental hospital is notified of the application for medicaid;

(c) The committee bases its assignment of the initial continued stay review date on—

(1) The methods and criteria required to be described under § 456.235(a);

(2) The individual's condition; and

(3) The individual's projected discharge date;

(d) (1) The committee uses any available appropriate regional medical care appraisal norms, such as those developed by abstracting services or third party payors, to assign the initial continued stay review date;

(2) These norms are based on current and statistically valid data on duration of stay in mental hospitals for patients whose characteristics, such as age and diagnosis, are similar to those of the individual whose need for continued stay is being reviewed;

(3) If the committee uses norms to assign the initial continued stay review date, the number of days between the individual's admission and the initial continued stay review date is no greater than the number of days reflected in the 50th percentile of the norms. However, the committee may assign a later review date if it documents that the later date is more appropriate;

(e) The initial continued stay review date is not in any case later than 30 days after admission of the individual or notice to the mental hospital of his application for medicaid; and

(f) The committee insures that the initial continued stay review date is recorded in the individual's record.

§ 456.234 Subsequent continued stay review dates

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.235(a) and 456.233;

(b) The committee assigns a subsequent continued stay review date at least every 90 days each time it decides under § 456.236 that the continued stay is needed; and

(c) The committee insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.235 Description of methods and criteria: Continued stay review dates; length of stay modification.

The UR plan must describe—

(a) The methods and criteria, including norms if used, that the commitee uses to assign initial and subsequent continued stay review dates under §§ 456.233 and 456.234 of this subpart; and

(b) The methods that the committee uses to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.236 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the mental hospital, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.211 against the criteria developed under § 456.232 and applies close professional scrutiny to cases described under § 456.232(b).

(d) If the committee, subgroup of designee finds that a recipient's continued stay in the mental hospital is needed, the committee assigns a new continued stay review date in accordance with § 456.234;

(e) If the committee, subgroup or designee finds that a continued stay case does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continue stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending or staff physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending or staff physician does not present additional information or clarification of the need for the continued stay, the decision of the committe or subgroup is final; and

(h) If the attending of staff physician presents additional information or clarification, at least two physician members of the committee, one of whom is knowledgeable in the treatment of mental diseases, review the need for the continued stay. If they find that the recipient no longer needs impatient mental hospital services, their decision is final.

§ 456.237 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.236(f) through (h) is sent to—

(a) The hospital administrator;

(b) The attending or staff physician;

(c) The medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.238 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.237 of an adverse decision within 2 working days after the assigned continued stay review date, except as required under paragraph (b) of this section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.237 within 2 working days after the date of the final decision.

UR PLAN: MEDICAL CARE EVALUATION STUDIES

§ 456.241 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and profession-

ally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analysis of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.242 UR plan requirements for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the mental hospital;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient hospital care procedures.

§ 456.243 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the mental hospital's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the hospital; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the hospital, and the community.

§ 456.244 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate hospital data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) PSRO's;

(2) Fiscal agents;

(3) Other service providers; or

(4) Other appropriate agencies.

§ 456.245 Number of studies required to be performed.

The mental hospital must, at least, have one study in progress at any time and complete one study each calendar year.

Subpart E—Utilization Control: Skilled Nursing Facilities

§ 456.250 Scope.

(a) This subpart prescribes requirements for control of utilization of skilled nursing facility (SNF) services including requirements concerning—

(1) Certification of need for care;

(2) Medical evaluation and admission review;

(3) Plan of care;

(4) Utilization review plans; and

(5) Discharge plans.

§ 456.251 Definitions.

"Skilled nursing facility services" means those items and services defined in §§ 440.40 and 440.140 of this subchapter, but excludes those services if they are provided in Christian Science sanitoria.

"Medical care criteria" means predetermined elements against which aspects of the quality of a medical service may be compared. These criteria are developed by health professionals relying on their expertise and the professional health care literature.

Certification of Need for Care

§ 456.260 Physician certification and recertification of need for inpatient care.

(a) A physician must certify and recertify for each applicant or recipient that SNF services are or were needed.

(b) The certification must be made at the time of admission or, if an individual applies for assisance while in a SNF, before the medicaid agency authorizes payment.

(c) Recertification must be made at least every 60 days after certification.

Medical, Psychiatric, and Social Evaluation, and Admission Review

§ 456.270 Medical, psychiatric, and social evaluations.

(a) Before admission to a SNF or before authorization for payment, the attending physician must make—

(1) A medical evaluation of each applicant's or recipient's need for care in the SNF; and

(2) A plan of rehabilitation, where applicable.

(b) In a SNF that cares primarily for mental patients, appropriate professional personnel must make a psychiatric and a social evaluation of need for care.

(c) Each medical evaluation must include—

(1) Diagnoses;

(2) Summary of present medical findings;

(3) Medical history;

(4) Mental and physical functional capacity;

(5) Prognoses; and

(6) A recommendation by a physician concerning—

(i) Admission to the SNF; or

(ii) Continued care in the SNF for individuals who apply for medicaid while in the facility.

§ 456.271 Medicaid agency review of need for admission.

Medical and other professional personnel of the medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.270.

Plan of Care

456.280 Individual written plan or care.

(a) Before admission to a SNF or before authorization for payment, the attending physician must establish a written plan of care for each applicant or recipient in a SNF.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures recommended for the health and safety of the patient;

(5) Plans for continuing care, including review and modification to the plan of care; and

(6) Plans for discharge.

(c) The attending or staff physician and other personnel involved in the recipient's care must review each plan of care at least every 60 days.

§ 456.281 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the SNF, immediately upon completion of the evaluation or plan.

UTILIZATION REVIEW (UR) PLAN: GENERAL REQUIREMENT

§ 456.300 Scope.

Sections 456.301 through 456.345 of this subpart prescribe requirements for a written utilization review (UR) plan for each SNF providing medicaid services. Sections 456.305 and 456.306 prescribe administrative requirements; §§ 456.311 through 456.313 prescribe informational requirements; §§ 456.331 through 456.338 prescribe requirements for continued stay review; and §§ 456.341 through 456.345 prescribe requirements for medical care evaluation studies.

§ 456.301 UR plan required for skilled nursing facility services.

(a) The State plan must provide that each SNF furnishing inpatient services under the plan has in effect a written UR plan that provides for review of each recipient's need for the services that the SNF furnishes him.

(b) Each written SNF UR plan must meet the requirements under §§ 456.301 through 456.345.

UR PLAN: ADMINISTRATIVE REQUIREMENTS

§ 456.305 UR committee required.

The UR plan must—

(a) Provide for a committee to perform UR required under this subpart;

(b) Describe the organization, composition, and functions of this committee; and

(c) Specify the frequency of meetings of the committee.

§ 456.306 Organization and composition of UR committee; disqualification from UR committee membership.

(a) For the purpose of this subpart, "UR committee" includes any group organized under paragraphs (b) and (c) of this section.

(b) The UR committee must be composed of two or more physicians and assisted by other professional personnel and, in a SNF that cares primarily for mental patients, include at least one physician member who is knowledgeable in the diagnosis and treatment of mental diseases.

(c) The UR committee must be constituted as—

(1) A committee of individuals with SNF staff privileges;

(2) A group outside the SNF established by the local medical or osteopathic society and at least some of the hospitals and SNFs in the locality; or

(3) A group capable of performing utilization review and established and organized in a manner approved by the Secretary.

(d) The UR committee may not include any individual who—

(1) Is directly responsible for the care of patients whose care is being reviewed;

(2) Is employed by the SNF; or

(3) Has a financial interest in any SNF.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.311 Recipient information required for UR.

The UR plan must provide that each recipient's record includes information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) Date of admission and dates of application for and authorization of medicaid benefits if application is made after admission.

(d) The plan of care required under § 456.272.

(e) Initial and subsequent continued stay review dates described under §§ 456.333 and 456.334.

(f) Reasons and plan for continued stay if the attending physician believes continued stay is necessary.

(g) Other supporting material that the committee believes appropriate to be included in the record.

§ 456.312 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the committee; and

(b) The type and frequency of committee reports, and arrangements for their distribution to appropriate individuals.

§ 456.313 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.331 Continued stay review required.

The UR plan must provide for a review of each recipient's continued stay in the SNF to decide whether it is needed, in accordance with the requirements of §§ 456.332–456.338.

§ 456.332 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The committee develops written medical care criteria to assess the need for continued stay; and

(b) The committee develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.333 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the SNF under admission review requirements of this subpart, the committee assigns a specified date by which the need for his continued stay will be reviewed;

(b) If an individual applies for medicaid while in the SNF, the committee assigns the initial continued stay review date within one working day after the SNF is notified of the application for medicaid;

(c) The committee bases its assignment of the initial continued stay review date on the methods and criteria required to be described under § 456.335(a);

(d) The initial continued stay review date is either—

(1) Not later than 90 days after the date of the individual's admission or notice to the SNF of his application for medicaid, if the date is established using specific periods for diagnostic categories or categories based on functional capabilities; or

(2) Not later than 30 days after the date of the individual's admission or notice of application, if the date is established by another method; and

(e) The committee ensures that the initial continued stay review date is recorded in the individual's record.

§ 456.334 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The committee assigns subsequent continued stay review dates in accordance with §§ 456.333 and 456.335(a).

(b) The committee assigns subsequent continued stay review dates each time it decides under § 456.336 that the continued stay is needed—

(1) At least every 90 days if the dates are established using specific periods for diagnostic categories based on functional capabilities; or

(2) At least every 30 days for the first 90 days and at least every 90 days thereafter if the dates are established by another method; and

(c) The committee ensures that each continued stay review date that it assigns is recorded in the recipient's record.

§ 456.335 Description of methods and criteria: Continued stay review dates; lengh of stay modification.

The UR plan must describe—

(a) The methods and criteria that the committee uses to assign initial and subsequent continued stay review dates under §§ 456.333 and 456.334; and

(b) The methods used by the committee to modify an approved length of stay when the recipient's condition or treatment schedule changes.

§ 456.336 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The UR committee;

(2) A subgroup of the UR committee; or

(3) A designee of the UR committee;

(b) The committee, subgroup or designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date;

(c) For each continued stay of a recipient in the SNF, the committee, subgroup or designee reviews and evaluates the documentation described under § 456.311 against the criteria developed under § 456.332 and applies close professional scrutiny to cases described under § 456.332(b);

(d) If the committee, subgroup or designee finds that the recipient's continued stay in the SNF is needed, the committee assigns a new continued stay review date in accordance with § 456.334;

(e) If the committee, subgroup or designee finds that a continued stay does not meet the criteria, the committee or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the committee or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies the recipient's attending physician and gives him an opportunity to present his views before it makes a final decision on the need for the continued stay;

(g) If the attending physician does not present additional information or clarification of the need for the continued stay, the decision of the committee of subgroup is final; and

(h) If the attending physician presents additional information or clarification, at least two physician members of the committee review the need for the continued stay. In a SNF that cares primarily for mental patients, one of these two physicians must be knowledgeable in the treatment of mental diseases. If they find that the recipient no longer needs SNF services, their decision is final.

§ 456.337 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.336 (f) through (h) is sent to—

(a) The SNF administrator;

(b) The attending physician;

(c) The medicaid agency;

(d) The recipient; and

(e) If possible, the next of kin or sponsor.

§ 456.338 Time limits for final decision and notification of adverse decision.

The UR plan must provide that—

(a) The committee makes a final decision on a recipient's need for continued stay and gives notice under § 456.337 of an adverse decision within three working days after the assigned review date, except as required under paragraph (b) of the section.

(b) If the committee makes an adverse final decision on a recipient's need for continued stay before the assigned review date, the committee gives notice under § 456.337 within 2 working days after the date of the final decision.

UR Plan: Medical Care Evaluation Studies

§ 456.341 Purpose and general description.

(a) The purpose of medical care evaluation studies is to promote the most effective and efficient use of available health facilities and services consistent with patient needs and professionally recognized standards of health care.

(b) Medical care evaluation studies—

(1) Emphasize identification and analyses of patterns of patient care; and

(2) Suggest appropriate changes needed to maintain consistently high quality patient care and effective and efficient use of services.

§ 456.342 UR plan requirement for medical care evaluation studies.

(a) The UR plan must describe the methods that the committee uses to select and conduct medical care evaluation studies under paragraph (b)(1) of this section.

(b) The UR plan must provide that the UR committee—

(1) Determines the methods to be used in selecting and conducting medical care evaluation studies in the SNF;

(2) Documents for each study—

(i) Its results; and

(ii) How the results have been used to make changes to improve the quality of care and promote more effective and efficient use of facilities and services;

(3) Analyzes its findings for each study; and

(4) Takes action as needed to—

(i) Correct or investigate further any deficiencies or problems in the review process; or

(ii) Recommend more effective and efficient skilled nursing care procedures.

§ 456.343 Content of medical care evaluation studies.

Each medical care evaluation study must—

(a) Identify and analyze medical or administrative factors related to the SNF's patient care;

(b) Include analysis of at least the following:

(1) Admissions.

(2) Durations of stay.

(3) Ancillary services furnished, including drugs and biologicals.

(4) Professional services performed in the SNF; and

(c) If indicated, contain recommendations for change beneficial to patients, staff, the SNF and the community.

§ 456.344 Data sources for studies.

Data that the committee uses to perform studies must be obtained from one or more of the following sources:

(a) Medical records or other appropriate data.

(b) External organizations that compile statistics, design profiles, and produce other comparative data.

(c) Cooperative endeavors with—

(1) PSRO's;

(2) Fiscal agents;

(3) Other providers of services; or

(4) Other appropriate agencies.

§ 456.345 Number of studies required to be performed.

The SNF must, at least, have one study in progress at any time and complete one study each calendar year.

Discharge Plan

§ 456.346 Discharge plan.

(a) The UR committee must review each recipient's discharge plan.

(b) Each discharge plan must insure that the recipient has a planned program of post-discharge continuing care that takes his needs into account.

§ 456.347 Discharge planning procedures.

Each SNF must maintain discharge planning procedures that describe the following:

(a) The staff member of the SNF or the health, social, or welfare agency responsible for discharge planning.

(b) The authority of the member or agency, and the methods used in discharge planning, including the relationship with the SNF's staff.

(c) The time allowed for determining each recipient's need for discharge planning. The period must not be longer than 7 days after the day of admission.

(d) The period after which each recipient's discharge plan will be reevaluated.

(e) The local resources available to the SNF, the recipient, and the at-

tending physician to assist in developing and implementing discharge plans.

(f) The provisions for periodic review and reevaluation of the SNF's discharge planning program.

§ 456.348 Information about discharged recipients.

(a) When a recipient is discharged, the SNF must provide information that will insure the optimal continuity of care, such as—

(1) Current information relative to diagnoses;

(2) Prior treatment;

(3) Rehabilitation potential;

(4) Physician advice concerning immediate care; and

(5) Pertinent social information.

(b) This information must be provided to those persons who are responsible for the recipient's post-discharge care.

Subpart F—Utilization Control: Intermediate Care Facilities

§ 456.350 Scope.

This subpart prescribes requirements for control of utilization of intermediate care facility (ICF) services including requirements concerning—

(a) Certification of need for care;

(b) Medical evaluation and admission review;

(c) Plan of care; and

(d) Utilization review plans.

§ 456.351 Definition.

As used in this subpart:

"Intermediate care facility services" means those items and services furnished in an intermediate care facility as defined in §§ 440.140 and 440.150 of this subchapter, but excludes those services if they are provided in Christian Science sanitoria.

Certification of Need for Care

§ 456.360 Physician certification and recertification of need for inpatient care.

(a) A physician must certify and recertify for each applicant or recipient that ICF services are or were needed.

(b) The certification must be made at the time of admission or, if an individual applies for assistance while in an ICF, before the medicaid agency authorizes payment.

(c) Recertifications must be made at least every 60 days after certification.

Medical, Psychological, and Social Evaluations and Admission Review

§ 456.370 Medical, psychological, and social evaluations.

(a) Before admission to an ICF or before authorization for payment, an interdisciplinary team of health professionals must make a comprehensive medical and social evaluation and, where appropriate, a psychological evaluation of each applicant's or recipient's need for care in the ICF.

(b) In an institution for the mentally retarded or persons with related conditions, the team must also make a psychological evaluation of need for care. The psychological evaluation must be made before admission or authorization of payment, but not more than three months before admission.

(c) Each evaluation must include—

(1) Diagnoses;

(2) Summary of present medical, social, and where appropriate, developmental findings;

(3) Medical and social family history;

(4) Mental and physical functional capacity;

(5) Prognoses;

(6) Kinds of services needed;

(7) Evaluation by an agency worker of the resources available in the home, family and community; and

(8) A recommendation concerning—

(i) Admission to the ICF; or

(ii) Continued care in the ICF for individuals who apply for medicaid while in the ICF.

§ 456.371 Exploration of alternative services.

If the comprehensive evaluation recommends ICF services for an applicant or recipient whose needs could be met by alternative services that are currently unavailable, the facility must enter this fact in the recipient's record and begin to look for alternative services.

§ 456.372 Medicaid agency review of need for admission.

Medical and other professional personnel of the medicaid agency or its designees must evaluate each applicant's or recipient's need for admission by reviewing and assessing the evaluations required by § 456.370.

Plan of Care

§ 456.380 Individual written plan of care.

(a) Before admission to an ICF or before authorization for payment, a physician must establish a written plan of care for each applicant or recipient.

(b) The plan of care must include—

(1) Diagnoses, symptoms, complaints, and complications indicating the need for admission;

(2) A description of the functional level of the individual;

(3) Objectives;

(4) Any orders for—

(i) Medications;

(ii) Treatments;

(iii) Restorative and rehabilitative services;

(iv) Activities;

(v) Therapies;

(vi) Social services;

(vii) Diet; and

(viii) Special procedures designed to meet the objectives of the plan of care;

(5) Plans for continuing care, including review and modification of the plan of care; and

(6) Plans for discharge.

(c) The team must review each plan of care at least every 90 days.

§ 456.381 Reports of evaluations and plans of care.

A written report of each evaluation and plan of care must be entered in the applicant's or recipient's record—

(a) At the time of admission; or

(b) If the individual is already in the ICF, immediately upon completion of the evaluation or plan.

Utilization Review (UR) Plan: General Requirement

§ 456.400 Scope.

Sections 456.401 through 456.438 of this subpart prescribe requirements for a written utilitzation review (UR) plan for each ICF providing medicaid services. Sections 456.405 through 456.407 prescribe administrative requirements; §§ 456.411 through 456.413 prescribe informational requirements; and §§ 456.431 through 456.438 prescribe requirements for continued stay review.

§ 456.401 State plan UR requirements and options; UR plan required for intermediate care facility services.

(a) The State plan must provide that—

(1) UR is performed for each ICF that furnishes inpatient services under the plan;

(2) Each ICF has on file a written UR plan that provides for review of each recipient's need for the services that the ICF furnishes him; and

(3) Each written ICF UR plan meets requirements under §§ 456.401 through 456.438.

(b) The State plan must specify the method used to perform UR, which may be—

(1) Review conducted by the facility;

(2) Direct review in the facility by individuals—

(i) Employed by the medical assistance unit of the Medicaid agency; or

(ii) Under contract to the medicaid agency; or

(3) Any other method.

UR Plan: Administrative Requirements

§ 456.405 Description of UR review function: How and when.

The UR plan must include a written description of—

(a) How UR is performed in the ICF; and

(b) When UR is performed.

§ 456.406 Description of UR review function: Who performs UR; disqualification from performing UR.

(a) The UR plan must include a written description of who performs UR in the ICF.

(b) UR must be performed using a method specified under § 456.401(b) by a group of professional personnel that includes—

(1) At least one physician;

(2) In an ICF that cares primarily for mental patients, at least one individual knowledgeable in the treatment of mental diseases; and

(3) In an institution for the mentally retarded, a least one individual knowledgeable in the treatment of mental retardation.

(c) The group performing UR may not include any individual who—

(1) Is directly responsible for the care of the recipient whose care is being reviewed;

(2) Is employed by the ICF; or

(3) Has a financial interest in any ICF.

§ 456.407 UR responsibilities of administrative staff.

The UR plan must describe—

(a) The UR support responsibilities of the ICF's administrative staff; and

(b) Procedures used by the staff for taking needed corrective action.

UR PLAN: INFORMATIONAL REQUIREMENTS

§ 456.411 Receipient information required for UR.

The UR plan must provide that each recipient's record include information needed to perform UR required under this subpart. This information must include, at least, the following:

(a) Identification of the recipient.

(b) The name of the recipient's physician.

(c) The name of the qualified mental retardation professional (as defined under § 442.401 of this subchapter), if applicable.

(d) Date of admission, and dates of application for and authorization of medicaid benefits if application is made after admission.

(e) The plan of care required under § 456.372;

(f) Initial and subsequent continued stay review dates described under §§ 456.433 and 456.434.

(g) Reasons and plan for continued stay, if the attending physician or qualified mental retardation professional believes continued stay is necessary.

(h) Other supporting material that the UR group believes appropriate to be included in the record.

§ 456.412 Records and reports.

The UR plan must describe—

(a) The types of records that are kept by the group performing UR; and

(b) The type and frequency of reports made by the UR group, and arrangements for distribution of the reports to appropriate individuals.

§ 456.413 Confidentiality.

The UR plan must provide that the identities of individual recipients in all UR records and reports are kept confidential.

UR PLAN: REVIEW OF NEED FOR CONTINUED STAY

§ 456.431 Continued stay review required.

(a) The UR plan must provide for a review of each recipients continued stay in the ICF at least every 6 months to decide whether it is needed.

(b) The UR plan requirement for continued stay review may be met by—

(1) Reviews that are performed in accordance with the requirements of §§ 456.432 through 456.437; or

(2) Reviews that meet on-site inspection requirements under Subpart I if—

(i) The composition of the independent professional review team under Subpart I meets the requirements of § 456.406; and

(ii) Reviews are conducted as frequently as required under §§ 456.333 and 456.334.

§ 456.432 Evaluation criteria for continued stay.

The UR plan must provide that—

(a) The group performing UR develops written criteria to assess the need for continued stay.

(b) The group develops more extensive written criteria for cases that its experience shows are—

(1) Associated with high costs;

(2) Associated with the frequent furnishing of excessive services; or

(3) Attended by physicians whose patterns of care are frequently found to be questionable.

§ 456.433 Initial continued stay review date.

The UR plan must provide that—

(a) When a recipient is admitted to the ICF under admission review requirements of this subpart, the group performing UR assigns a specified date by which the need for his continued stay will be reviewed;

(b) The group performing UR bases its assignment of the intitial continued stay review date on the methods and critieria required to be described under § 456.435(a);

(c) The initial continued stay review date is—

(1) Not later than 6 months after admission; or

(2) Earlier than 6 months after admission, if indicated at the time of admission; and

(d) The group performing UR insures that the initial continued stay review date is recorded in the recipient's record.

§ 456.434 Subsequent continued stay review dates.

The UR plan must provide that—

(a) The group performing UR assigns subsequent continued stay review dates in accordance with § 456.435.

(b) The group assigns a subsequent continued stay review date each time it decides under § 456.436 that the continued stay is needed—

(1) At least every 6 months; or

(2) More frequently than every six months if indicated at the time of continued stay review; and

(c) The group insures that each continued stay review date it assigns is recorded in the recipient's record.

§ 456.435 Description of methods and criteria: Continued stay review dates.

The UR plan must describe the methods and criteria that the group performing UR uses to assign initial and subsequent continued stay review dates under §§ 456.433 and 456.434.

§ 456.436 Continued stay review process.

The UR plan must provide that—

(a) Review of continued stay cases is conducted by—

(1) The group performing UR; or

(2) A designee of the UR group;

(b) The group or its designee reviews a recipient's continued stay on or before the expiration of each assigned continued stay review date.

(c) For each continued stay of a recipient in the ICF, the group or its designee reviews and evaluates the documentation described under § 456.411 against the criteria developed under § 456.432 and applies close professional scrutiny to cases described under § 456.432(b);

(d) If the group or its designee finds that a recipient's continued stay in the ICF is needed, the group assigns a new continued stay review date in accordance with § 456.434;

(e) If the group or its designee finds that a continued stay case does not meet the criteria, the group or a subgroup that includes at least one physician reviews the case to decide the need for continued stay;

(f) If the group or subgroup making the review under paragraph (e) of this section finds that a continued stay is not needed, it notifies he recipient's attending physician or, in institutions for the mentally retarded, the recipient's qualified mental retardation professional, within 1 working day of its decision, and gives him 2 working days from the notification date to present his views before it makes a final deci-

sion on the need for the continued stay;

(g) If the attending physician or qualified mental retardation professional does not present additional information or clarification of the need for the continued stay, the decision of the UR group is final;

(h) If the attending physician or qualified mental retardation professional presents additional information or clarification, the need for continued stay is reviewed by—

(1) The physician member(s) of the UR group, in cases involving a medical determination; or

(2) The UR group, in cases not involving a medical determination; and

(i) If the individuals performing the review under paragraph (h) of this section find that the recipient no longer needs ICF services, their decision is final.

§ 456.437 Notification of adverse decision.

The UR plan must provide that written notice of any adverse final decision on the need for continued stay under § 456.436 (g) through (i) is sent to—

(a) The ICF administrator;

(b) The attending physician;

(c) The qualified mental retardation professional, if applicable;

(d) The medicaid agency;

(e) The recipient; and

(f) If possible, the next of kin or sponsor.

§ 456.438 Time limits for notification of adverse decision.

The UR plan must provide that the group gives notice under § 456.437 of an adverse decision not later than 2 days after the date of the final decision.

Subpart G—Inpatient Psychiatric Services for Individuals Under Age 21: Admission and Plan of Care Requirements

§ 456.480 Scope.

This subpart concerns admission and plan of care requirements that apply to inpatient psychiatric services for individuals under age 21 in hospitals, mental hospitals, skilled nursing facilities, and intermediate care facilities.

§ 456.481 Admission certification and plan of care.

If a facility provides inpatient psychiatric services to a recipient under age 21—

(a) The admission certification by the review team required in § 441.152 satisfies the requirement for physician certification of need for care in §§ 456.60, 456.160, 456.260, and 456.360; and

(b) The development and review of the plan of care required in § 441.154 satisfies the requirement for physician recertification of need for care in the sections cited in paragraph (a) and the requirement for establishment and periodic review of the plan of care in §§ 456.80, 456.180, 456.280, and 456.380.

(c) The plan of care must be established by the team described in § 441.156.

§ 456.482 Medical, psychiatric, and social evaluations.

If a facility provides inpatient psychiatric services to a recipient under age 21, the medical, psychiatric, and social evaluations required by §§ 456.170, 456.270, and 456.370 must be made by the team described in § 441.153.

Subpart H—Utilization Review Plans: FFP, Waivers, and Variances for Hospitals, Mental Hospitals, and Skilled Nursing Facilities

§ 456.500 Purpose.

For hospitals, mental hospitals and SNF's, this subpart—

(a) Prescribes conditions for the availability of FFP relating to UR plans;

(b) Prescribes conditions for granting a waiver of UR plan requirements; and

(c) Prescribes conditions for granting a variance in UR plan requirements for remote facilities.

§ 456.501 UR plans as a condition for FFP.

(a) Except when waived under §§ 456.505 through 456.508, FFP is not available in expenditures for medicaid services furnished by a hospital, mental hospital, or SNF unless the facility has in effect a UR plan that meets the utilization review requirements for medicare under sec. 1861(k) of the act.

(b) A facility that participates in medicare and medicaid must use the same UR standards and procedures and review committee for medicaid as it uses for medicare.

(c) A facility that does not participate in medicare must meet the UR plan requirements in subpart C, D, or E of this part, which are equivalent to the medicare UR plan requirements in §§ 405.1035, 405.1036, and 405.1137 of this chapter.

UR Plan: Waiver of Requirements

§ 456.505 Applicability of waiver.

The Administrator may waive the UR plan requirements of subparts C, D, or E of this part, except for provisions relating to disqualification of UR committee members under § 456.106 of subpart C, § 456.206 of subpart D, and § 456.306 of subpart E, if the medicaid agency—

(a) Applies for a waiver; and

(b) Demonstrates to the Administrator's satisfaction that it has in operation specific UR procedures that are superior in their effectiveness to the UR plan requirements under subparts C, D, or E.

§ 456.506 Waiver options for medicaid agency.

(a) The agency may apply for a waiver at any time it has the procedures referred to under § 456.505(b) in operation at least—

(1) On a demonstration basis; or

(2) In any part of the State.

(b) Any hospital, mental hospital, or SNF participating under the plan that is not covered by a waiver must continue to meet all the UR plan requirements under subpart C, D, or E of this part.

§ 456.507 Review and granting of waiver requests.

(a) When the agency applies for a waiver, the Administrator will assess the agency's UR procedures and grant the waiver if he determines that the procedures meet criteria he establishes.

(b) The Administrator will review and evaluate each waiver between 1 and 2 years after he has granted it and between 1 and 2 years periodically thereafter.

§ 456.508 Withdrawal of waiver.

(a) The Administrator will withdraw a waiver if he determines that State procedures are no longer superior in their effectiveness to the procedures required for UR plans under subparts C, D, or E.

(b) If a waiver is withdrawn by the Administrator, each hospital, mental hospital, or SNF covered by the waiver must meet all the UR plan requirements under subparts C, D, or E of this part.

UR Plan: Remote Facility Variances From Time Requirements

§ 456.520 Definitions.

As used in §§ 456.521 through 456.525 of this subpart:

"Available physician or other professional personnel" means an individual who—

(a) Is professionally qualified;

(b) Is not precluded from participating in UR under § 456.107 of subpart C; § 456.207 of subpart D; or § 456.307 of subpart E; and

(c) Is not precluded from effective participation in UR because he requires more than approximately 1 hour to travel between the remote facility and his place of work.

"Remote facility" means a facility located in an area that does not have enough available physicians or other professional personnel to perform UR as required under subparts C, D, or E of this part, and for which the State requests a variance.

"Variance" means permission granted by the Administrator to the medicaid agency for a specific remote facility to use time periods different from those specified for the start and completion of reviews of all cases under the following sections: Sections 456.125, 456.126, 456.136, and 456.137 of subpart C; § 456.238 of subpart D; and §§ 456.333, 456.334, and 456.336 of subpart E.

§ 456.521 Conditions for granting variance requests.

(a) Except as described under paragraph (b) of this section, the administrator may grant a variance for a specific remote facility if the agency submits concurrently—

(1) A request for the variance that documents to his satisfaction that the facility is unable to meet the time requirements for which the variance is requested; and

(2) A revised UR plan for the facility.

(b) The Administrator will not grant a variance if the remote facility is operating under a UR plan waiver that the Secretary has granted or is considering under §§ 456.505 through 456.508.

§ 456.522 Content of request for variance.

The agency's request for a variance must include—

(a) The name, location, and type of the remote facility;

(b) The number of total patient admissions and the average daily patient census at the facility in the 6 months preceding the request;

(c) The number of medicare and medicaid patient admissions and the average daily medicare and medicaid patient census at the facility in the 6 months preceding the request;

(d) The name and location of each hospital, mental hospital, SNF, and ICF located within a 50-mile radius of the facility;

(e) The distance and average travel time between the remote facility and each facility listed in paragraph (e) of this section;

(f) Documentation by the facility of its attempts to obtain the services of available physicians or other professional personnel, or both;

(g) The names of all physicians on the active staff, and the names of all other professional personnel on the staff whose availability is relevant to the request;

(h) The practice locations of available physicians and the estimated number of available professional personnel whose availability is relevant to the request;

(i) Documentation by the facility of its inability to perform UR within the time requirements for which the variance is requested and its good faith efforts to comply with the UR plan requirements of subparts C, D, or E of this part;

(j) An assurance by the facility that it will continue its good faith efforts to meet the UR plan requirements of subpart C, D, or E of this part; and

(k) A statement of whether a planning or conditional PSRO exists in the area where the facility is located.

§ 456.523 Revised UR plan.

(a) The revised UR plan for the remote facility must specify the methods and procedures that the facility will use if a variance is granted to insure that it—

(1) Maintains effective and timely control over the utilization of services; and

(2) Conducts reviews in a way that improves the quality of care provided to patients.

(b) The revised UR plan for the remote facility is the basis for validation of UR under sec. 1903(g)(2) of the Act for the period when a variance is in effect.

§ 456.524 Notification of Administrator's action and duration of variance.

(a) The Administrator—

(1) Will notify the agency of the action he takes on its request for a variance; and

(2) Will specify the period of time, not to exceed 1 year, for which the variance may be granted.

(b) When it receives the Administrator's notification, the agency must promptly notify the remote facility of his action.

§ 456.525 Request for renewal of variance.

(a) The agency must submit a request for renewal of a variance to the Administrator at least 30 days before the variance expires.

(b) The renewal request must contain the information required under § 456.522.

(c) The renewal request must show, to the Administrator's satisfaction, that the remote facility continues to meet the requirements of §§ 456.521 through 456.523.

Subpart I—Inspections of Care in Skilled Nursing and Intermediate Care Facilities and Institutions for Mental Diseases

§ 456.600 Purpose.

This subpart prescribes requirements for periodic inspections of care and services in skilled nursing facilities (SNF's), intermediate care facilities (ICF's), and institutions for mental diseases (IMD's).

§ 456.601 Definitions.

For purposes of this subpart—

"Facility" means a skilled nursing facility, an institution for mental diseases, or an intermediate care facility.

"Intermediate care facility" includes institutions for the mentally retarded or persons with related conditions but excludes Christian Science sanatoria operated, or listed and certified, by the First Church of Christ Scientist, Boston, Mass.

"Institution for mental diseases" includes a mental hospital, a psychiatric facility, and a skilled nursing or intermediate care facility that primarily cares for mental patients.

"Psychiatric facility" includes a psychiatric program as defined in subpart D of Part 441.

§ 456.602 Inspection team.

(a) A team, as described in this section and § 456.603 must periodically inspect the care and services provided to recipients in each facility.

(b) Each team conducting periodic inspections must have a least one member who is at physician or registered nurse and other appropriate health and social service personnel.

(c) For an IMD other than an ICF, each team must have a psychiatrist or physician knowledgeable about mental institutions and other appropriate mental health and social service personnel.

(d) For an ICF that primarily cares for mental patients, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(e) For an institution for the mentally retarded or persons with related conditions, each team must have at least one member who knows the problems and needs of mentally retarded individuals.

(f) For ICFs primarily serving individuals 65 years of age or older, each team must have at least one member who knows the problems and needs of those individuals.

(g) If there is no physician on the team, the medicaid agency must insure that a physician is available to provide consultation to the team.

(h) If a team has one or more physicians, it must be supervised by a physician.

§ 456.603 Financial interests and employment of team members.

(a) Except as provided in paragraph (b) of this section—

(1) No member of a team that reviews care in a SNF may have a finan-

cial interest in or be employed by any SNF; and

(2) No member of a team that reviews care in an ICF may have a financial interest in or be employed by any ICF.

(b) A member of a team that reviews care in an IMD or an institution for the mentaly retarded or persons with related conditions—

(1) May not have a financial interest in any institution of that same type but may have a financial interest in other facilities or institutions; and

(2) May not review care in an institution where he is employed but may review care in any other facility or institution.

§ 456.604 Physician team member inspecting care of recipients.

No physician member of a team may inspect the care of a recipient for whom he is the attending physician.

§ 456.605 Number and location of teams.

There must be a sufficient number of teams so located within the State that onsite inspections can be made at appropriate intervals in each facility caring for recipients.

§ 456.606 Frequency of inspections.

The team and the agency must determine, based on the quality of care and services being provided in a facility and the condition of recipients in the facility, at what intervals inspections will be made. However, the team must inspect the care and services provided to each recipient in the facility at least annually.

§ 456.607 Notification before inspection.

No facility may be notified of the time of inspection more than 48 hours before the scheduled arrival of the team.

§ 456.608 Personal contact with and observation of recipients and review of records.

(a) For recipients under age 21 in psychiatric facilities and recipients in SNFs and ICFs, other than those described in paragraph (b) of this section, the team's inspection must include—

(1) Personal contact with and observation of each recipient; and

(2) Review of each recipient's medical record.

(b) For recipients age 65 or older in IMDs, the team's inspection must include—

(1) Review of each recipient's medical record; and

(2) If the record does not contain complete reports of periodic assessments required by 45 CFR 208.1(a)(2) or if such reports are inadequate, personal contact with and observation of each recipient.

§ 456.609 Determinations by team.

The team must determine in its inspection whether—

(a) The services available in the facility are adequate to—

(1) Meet the health needs of each recipient, and the rehabilitative and social needs of each recipient in an ICF; and

(2) Promote his maximum physical, mental, and psychosocial functioning.

(b) It is necessary and desirable for the recipient to remain in the facility;

(c) It is feasible to meet the recipient's health needs and, in an ICF, the recipient's rehabilitative needs, through alternative institutional or noninstitutional services; and

(d) Each recipient under age 21 in a psychiatric facility and each recipient in an institution for the mentally retarded or persons with related conditions is receiving active treatment as defined in § 441.154 of this subchapter.

§ 456.610 Basis for determinations.

In making the determinations on adequacy of services and related matters under § 456.609 for each recipient, the team may consider such items as whether—

(a) The medical evaluation, any required social and psychological evaluations, and the plan of care are complete and current; the plan of care and, where required, the plan of rehabilitation are followed; and all ordered services, including dietary orders, are provided and properly recorded;

(b) The attending physician reviews prescribed medications—

(1) At least every 30 days in SNFs, psychiatric facilities, and mental hospitals; and

(2) At least quarterly in ICFs;

(c) Tests or observations of each recipient indicated by his medication regimen are made at appropriate times and properly recorded;

(d) Physician, nurse, and other professional progress notes are made as required and appear to be consistent with the observed condition of the recipient;

(e) The recipient receives adequate services, based on such observations as—

(1) Cleanliness;

(2) Absence of bedsores;

(3) Absence of signs of malnutrition or dehydration; and

(4) Apparent maintenance of maximum physical, mental, and psychosocial funtion;

(f) In an ICF, the recipient receives adequate rehabilitative services, as evidenced by—

(1) A planned program of activities to prevent regression; and

(2) Progress toward meeting objectives of the plan of care;

(g) The recipient needs any service that is not furnished by the facility or through arrangements with others; and

(h) The recipient needs continued placement in the facility or there is an appropriate plan to transfer the recipient to an alternate method of care.

§ 456.611 Reports on inspections.

(a) The team must submit a report promptly to the agency on each inspection.

(b) The report must contain the observations, conclusions, and recommendations of the team concerning—

(1) The adequacy, appropriateness, and quality of all services provided in the facility or through other arrangements, including physician services to recipients; and

(2) Specific findings about individual recipients in the facility.

§ 456.612 Copies of reports.

The agency must send a copy of each inspection report to—

(a) The facility inspected;

(b) The facility's utilization review committee;

(c) The agency responsible for licensing, certification, or approval of the facility for purposes of medicare and medicaid; and

(d) Other State agencies that use the information in the reports to perform their official function, including, if inspection reports concern IMD's, the appropriate State mental health authorities.

§ 456.613 Action on reports.

The agency must take corrective action as needed based on the report and recommendations of the team submitted under this subpart.

§ 456.614 Inspections by utilization review committee.

A utilization review committee under subparts C through F of this part may conduct the periodic inspections required by this subpart if—

(a) The committee is not based in the facility being reviewed; and

(b) The composition of the committee meets the requirements of this subpart.

(Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program.)

Dated: August 22, 1978.

WILLIAM D. FULLERTON,
Acting Administrator, Health, Care Financing Administration.

Approved: September 24, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

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FRIDAY, SEPTEMBER 29, 1978
PART VI

DEPARTMENT OF COMMERCE

DEPARTMENT OF TRANSPORTATION

■

FLOODPLAIN MANAGEMENT AND PROTECTION OF WETLANDS

Implementation of Executive Orders 11988 and 11990

[3510-17]

DEPARTMENT OF COMMERCE

Office of the Secretary

[Dept. Administrative Order 216-11; Transmittal 308]

FLOODPLAIN AND WETLANDS EXECUTIVE ORDERS

Availability for Public Comment on Department of Commerce Procedures for Implementation

AGENCY: U.S. Department of Commerce.

ACTION: Notice of availability for public comment on departmentwide procedures for implementation of the floodplain and wetlands Executive orders.

SUMMARY: The Department of Commerce is making available for public review and comment the procedures (U.S. Department of Commerce Administrative Order No. 216-11) it will use to implement Executive Order 11988, Floodplain Management, and Executive Order 11990, Protection of Wetlands. Both orders required all Federal agencies to review their activities, procedures, and rules and regulations. The Department of Commerce procedures for these orders provide that the heads of organization units with programs that may produce impacts on floodplains or wetlands shall issue specific procedures for complying with the Executive orders.

DATE: Comments must be received on or before October 30, 1978.

ADDRESS: All comments should be sent to Executive Secretariat, U.S. Department of Commerce, Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT:

Dr. Sidney R. Galler, Office of Environmental Affairs, U.S. Department of Commerce, Washington, D.C. 20230, phone 202-377-4335.

SUPPLEMENTARY INFORMATION:

Executive Order 11988, Floodplain Management, affirmed that it is the policy to protect and enhance the natural and beneficial values of floodplains and to actively discourage noncompatible development. The Executive Order 11990, for protection of wetlands, recognized that our remaining wetlands are a valuable national resource. All Federal agencies are to do everything possible to avoid direct or indirect support on new construction in wetlands wherever there is a practical alternative.

The U.S. Water Resources Council's Floodplain Management Guidelines for Implementing E.O. 11988 (43 FR 6030, Feb. 10, 1978) provide the basic implementation guidelines. The Commerce procedures incorporate the Water Resources Council's guidelines and insure that all Department of Commerce actions further the intent and purpose of both Presidential Executive orders.

Subject: Floodplain Management and Protection of Wetlands. This order is effective September 11, 1978.

SECTION 1. PURPOSE

The purpose of this order is to prescribe the Department of Commerce policies and procedures for implementing Executive Orders 11988 and 11990.

SECTION 2. SCOPE

On May 24, 1977, the President issued Executive Orders 11988 (Floodplain Management) and 11990 (Protection of Wetlands). These Orders direct Federal agencies to avoid, to the extent possible, all actions associated with the modification or destruction of floodplains and wetlands, or that may increase the risk of loss of life and property resulting from flood and storm damage.

SECTION 3. DEFINITIONS

.01 *Flood or flooding* is a general and temporary condition of partial or complete inundation of normally dry land areas from the overflow of inland and/or tidal waters, and/or the unusual and rapid accumulation or runoff of surface waters from any source.

.02 *Floodplains.* Floodplains are lowland and relatively flat areas adjoining inland and coastal waters including flood prone areas of offshore islands, including at a minimum, that area subjet to a one percent or greater chance of flooding in any given year. The term floodplain shall be taken to mean the *base floodplain* unless the action is a critical action, in which case the *critical action floodplain* is a minimum floodplain of concern.

a. *Base floodplain* (or 100-year floodplain)—the area subject to inundation from a flood of a magnitude that occurs once every 100 years on the average (1.0 percent chance flood).

b. *Critical action floodplain* (or 500-year floodplain)—the area subject to ununcation from a flood of a magnitude that occurs once every 500 years on the average (0.2 percent chance flood).

.03 *Wetlands.* Wetlands are those areas that are inundated by surface or ground water with a frequency sufficient to support and under normal circumstances does or would support a prevalence of vegetation or aquatic life that requires saturated or seasonally saturated soil conditions for growth and reproduction. Examples of wetlands include swamps, fresh and salt water marshes, beaches, bogs, sloughs, potholes, wet meadows, mud flats, river overflows, natural ponds, as well as areas separated from their natural supply of water through man-made alterations such as dikes, berms, floodwalls, and levees.

.04 *Organization unit.* As used in this order, organization unit(s) means all Departmental offices and operating units of the Department of Commerce with program responsibilities subject to the floodplain and wetland Executive Orders.

.05 *Action.* An action is any Department activity including:

(a) acquiring, managing, and disposing of Federal lands and facilities;

(b) providing financial assistance including, but not limited to, grants, loans, contracts, subsidies, and guarantees or amendments to such forms of assistance for the acquisition of land and the construction of facilities and improvements; and

(c) conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating and licensing activities.

.06 *Critical action.* A critical action is an action which, if located in a floodplain, poses a greater than normal risk for flood-caused loss of life or property. The minimum floodplain of concern for critical actions is the 500-year floodplain. Critical actions include, but are not limited to, actions which create facilities or extend the useful life of facilities:

(a) which produce, use, or store highly volatile, flammable, explosive, toxic, or water-reactive materials;

(b) such as schools, hospitals, and nursing homes, which are likely to contain occupants who may not be sufficiently mobile to avoid the loss of life or injury should flooding occur; and

(c) such as emergency operation centers, essential public utilities, and data storage centers, which contain records or services that may become lost or inoperative should flooding occur.

.07 *Related activities.* Related activities are those undertakings that are interdependent parts of an action. They either make possible or support an action, or are themselves induced or supported by an action or related activities. Related activities may or may not be federally permitted or assisted.

.08 *Impacts.* Impacts are changes in flood plain or wetland values and functions. Impacts may occur as either direct or indirect results of an action. Impacts are a direct result of an action whenever the action causes a change in floodplain or wetland values and functions. Impacts are an indirect result of an action whenever an action induces or makes possible related activities which affect the natural values and functions of floodplains or wetlands.

.09 *Alternatives.* Alternatives are those actions, in addition to the proposed action, with similar benefits and which eliminate or minimize impacts on a floodplain or wetland.

.10 *Minimize.* Minimize means to reduce to the smallest amount or degree practicable.

.11 *Mitigation measures.* Mitigation measures are measures to minimize the impacts of the proposed action on a floodplain or wetland, including measures to preserve and, wherever practicable, restore natural values and functions. Examples of mitigation measures include, but are not limited to:

(a) floodplain or wetland habitat restoration;

(b) collecting and treating runoff resulting from an action prior to its discharge into a floodplain or a wetland;

(c) establishing a vegetative buffer zone between the site of a proposed action and adjacent floodplains or wetlands; or

(d) improving habitat values and functions through management.

.12 *Practicable.* Practicable is defined as an action capable of being performed within

existing constraints. This test depends upon the particular situation and the constraints imposed by environmental, economic, legal, and technological considerations. However, the test is *not* limited by the temporary unavailability of sufficient financial resources to implement either an alternative to a proposed action or a mitigation measure necessary to minimize impact. Thus, alternatives or mitigation measures shall not be rejected as "impracticable" solely on the basis of an increase in cost.

SECTION 4. POLICY

.01 The head of each organization unit shall insure that all of its activities related to this order are conducted in accordance with Executive Orders 11988 and 11990 and the Water Resources Council's "Floodplain Management Guidelines" (43 FR 6030). The heads of organization units with programs that may produce impacts on floodplains or wetlands shall issue specific procedures for complying with the Executive Orders. It shall be the responsibility of the heads of all organization units to devise mechanisms and to inform all prospective participants in their programs of the intent of Executive Orders 11988 and 11990 and the Department's policy as stated in this order.

.02 No organization unit shall participate in any action that would impact a floodplain or wetland until that organization unit determines that no practicable alternative exists to the action. In this case, the no action alternative shall be considered. Where a determination is made that no practicable alternative exists to impacting a floodplain or wetland and the no action alternative is unacceptable, the organization unit shall ensure that the action choses is the alternative which minimizes those impacts, *and* that all practicable mitigation measures are incorporated into the action which:

(a) minimize the risks of loss of life and property due to flood and storm damage; and

(b) minimize the adverse impacts on floodplain and wetland values and functions.

.03 Whenever an action requires locating in a floodplain or wetland area, each organization unit shall require locating the action, if practicable, within the floodplain and not within the wetland.

.04 The following proposed actions that impact wetlands not located within the floodplain are exempt from these procedures:

a. Federally assisted or permitted actions under construction prior to the effective date of this order; or

b. Federal actions for which a draft or final Environmental Impact Statement (EIS) was filed prior to October 1, 1977.

.05 Each organization unit, in carrying out this policy, shall insure that its actions are consistent with State coastal zone management programs as approved by the Secretary under the Coastal Zone Management Act of 1972 as amended (16 U.S.C. 1451 *et seq.*). Each organization unit shall also insure that its actions are in compliance with Section 10 of the Rivers and Harbors Act of 1899 and with Section 404 of the Clean Water Act of 1977 which require Department of the Army permits for construction and disposal of dredged material in waters of the United States, including adjacent wetlands (33 CFR 320-340).

SECTION 5. PROCEDURES.

.01 Organization Unit Responsibilities.

(a) The Deputy Assistant Secretary for Environmental Affairs shall serve as the focal point in the Department for implementing the requirements of this order.

(b) Each organization unit in implementing DAO 216-6 shall in addition determine whether the action under consideration is located in or would otherwise impact a floodplain or wetland. The determination shall be made in accordance with the Water Resources Council's "Guidance for Determining a Floodplain Location," (Vol. 42 FR 52590-52599, September 30, 2977).

(c) If a determination is made that a floodplain or wetland is impacted, each organization unit shall:

1. Determine if there is a practicable alternative which would avoid such impact. If no such alternative exists, determine if there is a practicable alternative which minimizes the impact on floodplains and wetlands; and

2. Identify and analyze resulting impacts including impacts on public health, safety and welfare; and floodplain and wetland natural values and functions.

.02 Public Notification Requirements.

(a) If it is determined that a proposed action would impact a floodplain or wetland, each organization unit shall insure that a notice of the proposed action is published in the newspaper of greatest circulation in the vicinity of the proposed action. The notice shall appear for at least three consecutive days and shall include a physical description of the location and surrounding area and the nature and extent of the proposed action. Attempts should also be made to inform the community, by publication or other means, in the area where the impact of the proposed action will occur. The organization unit shall allow at least 30 days from the publication date of the last required notice for receipt of public comments.

(b) The organization unit shall arrange for a public meeting to discuss the action where the organization unit determines that a public meeting will serve the public interest. The organization unit shall insure that at least two notices of such public meeting are published in the newspaper having the greatest circulation in the vicinity of the proposed action. Wherever possible, the community in the action's area of impact shall also be informed. The first of the required notices shall be published 15 to 20 days before the meeting date, and the second notice 2 to 4 days before the meeting date. Such notice shall include the location, date, and time of the meeting, a description of the proposed action's location and the surrounding area, and a brief description of the proposed action. In addition, copies of the notices shall be mailed to appropriate local, State and Federal agencies, public interest groups, news media, and any other agencies, groups, or individuals who have an interest in the action. If a public meeting is held conerning a proposal which requires an EIS, the meeting shall not be held until at least 15 days have elapsed from the date of publication of the draft EIS. The organization unit shall insure that a written transcript of the meeting is prepared.

(c) Each organization unit shall coordinate publication activities under this order with the Office of Public Affairs.

(d) In coorinating organization unit procedures under this order and DAO 216-6, each organization unit may establish additional public notification and consultative procedures, as appropriate, or as required by other authorities.

.03 Final Notice and Findings.

Upon determination of the practicable alternative and mitigation measures, the organization unit shall insure the publication of a final notice of the proposed action. The notice shall be published in the newspaper of greatest circulation in the vicinity of the proposed action for at least 3 consecutive days, and shall include a physical description of the location and surrounding area, a detailed description of the proposed action, the measures used to mitigate impacts, and the projected date of the action's initiation and completion. Attempts should also be made to inform the community, by publication or other means, in the area where the impact of the proposed action will occur The organization unit shall wait 15 days after publication of final notice before initiating the action.

ELSA A. PORTER,
Assistant Secretary for Administration.

[FR Doc. 78-27722 Filed 9-28-78; 8:45 am]

[4910-62]

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Notice 78-11]

PRESERVATION OF WETLANDS

Issuance of Internal Order

AGENCY: Department of Transportation (DOT).

ACTION: Notice of issuance of internal order.

SUMMARY: DOT herewith publishes for the information of the public its internal order implementing Executive Order 11990, Preservation of Wetlands.

EFFECTIVE DATE: August 24, 1978.

FOR FURTHER INFORMATION CONTACT

Martin Convisser, Director, Office of Environment and Safety, Office of the Assistant Secretary for Policy and International Affairs, Department of Transportation, 400 Seventh Street SW. Washington, D.C. 20590, 202-426-4357.

SUPPLEMENTARY INFORMATION: The principal drafter of the order is Sonya Hill, Office of Environment and Safety.

Issued in Washington, D.C., on September 22, 1978.

MARTIN CONVISSER,
Director, Office of Environment and Safety.

DEPARTMENT OF TRANSPORTATION

[Order 5660.1A]

PRESERVATION OF THE NATION'S WETLANDS

1. *Purpose.* This order sets forth the Department of Transportation (DOT) policy that transportation facilities and projects should be planned, constructed, and operated to assure the protection, preservation, and enhancement of the nation's wetlands to the fullest extent practicable, and establishes procedures for implementation of the policy.

2. *Cancellation.* DOT 5660.1, Preservation of the Nation's Wetlands, of 5-21-75.

3. *Background and Authority.* This order is issued pursuant to the following Executive Order and statutes:

(a) Executive Order 11990, dated May 24, 1977, "Protection of Wetlands," establishes a national policy "to avoid to the extent possible the long- and short-term adverse impacts associated with the destruction or modification of wetlands and to avoid direct or indirect support of new construction in wetlands wherever there is a practicable alternative." The order further provides that each agency shall provide leadership to minimize the destruction, loss, or degradation of wetlands and to preserve and enhance the natural and beneficial values of wetlands in carrying out the agency's responsibilities for (1) acquiring, managing, and disposing of federal lands and facilities, (2) providing federally undertaken, financed, or assisted construction and improvements, and (3) conducting federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities.

(b) Sections 2 (b) and 4(f) of the Department of Transportation Act of 1966 (49 U.S.C. 1651 et seq.) provide that it is "national policy that special effort should be made to preserve the natural beauty of the countryside and the park and recreation lands, wildlife and waterfowl refuges, and historic sites."

(c) The National Environmental Policy Act of 1969 (NEPA) as amended (42 U.S.C. 4321 et seq.) establishes a national policy to "* * * promote efforts which will prevent or eliminate danger to the environment and biosphere and stimulate the health and welfare of man * * *." NEPA requires preparation of an environmental impact statement (EIS) for any major Federal action significantly affecting the quality of the human environment. Order DOT 5610.1B, "Procedures for Considering Environmental Impacts," of September 30, 1974, requires that information on impacts on fresh water and coastal wetlands be included in the EISs prepared pursuant to NEPA.

d. Section 2 of the Fish and Wildlife Coordination Act (16 U.S.C. 661 et seq.) provides for consultation with the U.S. Fish and Wildlife Service and the State wildlife resources agency when "* * * waters of any stream or other body of water are proposed to be controlled or modified * * *."

e. The Water Bank Act (16 U.S.C. 1301) expresses the congressional finding that "it is in the public interest to preserve, restore, and improve the wetlands of the nation * * *."

f. The Coastal Zone Management Act (16 U.S.C. 145) establishes a policy to "preserve, protect, and develop natural resources of the coastal zone and where possible to restore them."

g. The Federal Water Pollution Control Act Amendments 1972 (33 U.S.C. 1151) establish a policy to "restore and maintain the chemical, physical, and biological intergrity of the Nation's waters."

4. *Definition.*

a. Wetlands are defined as lowlands covered with shallow and sometimes temporary or intermittent waters. This includes, but is not limited to, swamps, marshes, bogs, sloughs, potholes, wet meadows, river overflows, and tidal overflows, as well as estuarine areas, and shallow lakes and ponds with emergent vegetation. Areas covered with water for such a short time that there is no effect on moist-soil vegetation are not included in the definition, nor are the permanent waters of streams, reservoirs, and deep lakes. The wetlands ecosystem includes those areas which affect or are affected by the wetland area itself; e.g., adjacent uplands or regions up and down stream. An activity may affect the wetlands indirectly by impacting regions up or down stream from the wetland or by disturbing the water table of the area in which the wetland lies. Attachment 1 references the wetlands classification system.

b. "New construction" for purposes of this order shall include any draining, dredging, channelizing, filling, diking, impounding, and related activities, and any structures or facilities begun or authorized after the effective date of this order. This does not include routine repairs and maintenance of existing facilities.

5. *Policy.* It is the policy of DOT to assure the protection, preservation, and enhancement of the Nation's wetlands to the fullest extent practicable during the planning, construction, and operation of transportation facilities and projects. In accordance with E.O. 11990, new construction located in wetlands shall be avoided unless there is no practicable alternative to the construction and the proposed action includes all practicable measures to minimize harm to wetlands which may result from such contruction. In making a finding of no practicable alternative, economic, environmental and other factors may be taken into account. Some additonal cost alone will not necessarily render alternatives or minimization measures impractical since additonal cost would normally be recognized as necessary and justified to meet national wetland policy objectives.

6. *Responsibilities.*

a. The Assistant Secretary for Policy and International Affairs (P-1) shall oversee the implementation of the policy set forth in this order, shall recommend any modifications of procedures that may be appropriate, and shall consult with the Department of the Interior, the Council on Environmental Quality, and other agenices as appropriate concerning the Department's implementation of these policies.

b. Heads of operating administrations shall distribute this order or promulgate appropriate guidance consistent with this order and the Executive Order and shall be responsible for the full implementation of the policies within their respective administrations.

c. The Assistant Secretary (P-1) and the heads of operating administrations jointly shall be responsible for preparation and/or dissemination of appropriate guidance, informational materials, training programs, and other materials necessary to comply with the Executive order's requirement that agencies provide leadership in the field of wetland protection. Such leadership should be particularly aimed at informing and guiding the actions of State and local transportation officials operating with the assistance of or subject to permits from DOT.

7. *Procedures.* The following procedures should be integrated into existing environmental and public participation processes to the maximum extent feasible. The policy of this order applies to any project located in or having an impact on wetlands.

a. New authorizations or appropriations transmitted to the Office of Management and Budget will indicate, if a specific action to be proposed will be located in wetlands, whether the proposed action is in accord with E.O. 11990.

b. The impacts of new construction projects on wetlands should be identified and discussed in any submissions made to State and metropolitan clearinghouses under Office of Management and Budget Circular A-95. Submissions to A-95 will not be required solely to address wetland issues. Appropriate opportunity for early review of proposals for new construction in wetlands should be provided to the public and to agencies with special interest in wetlands. This may include early public involvement approaches.

c. Any project which will have a significant impact on wetlands will require preparation of an EIS. Prior to the preparation of an EIS, agencies with jurisdiction and expertise concerning wetland impacts (U.S. Fish and Wildlife Service, State wildlife or natural resources agencies, and the Corps of Engineers, as appropriate) should be consulted for advice and assistance concerning the proposed undertaking.

d. An EIS (or negative declaration) on a proposal for new construction in wetlands should reflect the results of early coordination and should identify specific impacts of the project on the wetlands taking into consideration the matters listed in paragraph 6(f).

e. When federally owned wetlands or portions of wetlands are proposed for lease, easement, right-of-way, or disposal to non-Federal public or private parties, the agency with jurisdiction over the lands should either (1) reference in the conveyance those uses that are restricted under this policy and other relevant Federal, State, or local wetlands regulations; or (2) attach other appropriate restrictions to the use of properties by the grantee or purchaser and any successor, except where prohibited by law; or (3) withhold such properties from disposal.

f. In carrying out any activities (including small scale projects which do not require documentation) with a potential effect on wetlands, operating agencies should consider the following factors in implementing the Department policy relevant to a proposal's effect on the survival and quality of wetland:

(1) Public health, safety, and welfare, including water supply, water quality, recharge and discharge, and pollution; flood and storm hazards; and sedimentation and erosion.

(2) Maintenance of natural systems, including conservation and long-term activity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, fish and wildlife, timber, and food and fiber resources; and other uses of wetlands in the public interest, including recreational scientific, and cultural uses as well as transportation uses and objectives.

g. Alternatives which would avoid new construction in wetlands must be studied, giving consideration to environmental and economic factors. If uses of wetlands is proposed, the alternatives analysis for major actions should have demonstrated that there is no practicable alternative to the use of the wetlands and that all practicable measures to minimize harm to the wetlands have been included.

h. For any major action which entails new construction located in wetlands, a specific finding should be made by the affected operating administration that (1) there is no practicable alternative to construction in the wetland and (2) that all practicable measures to mininmize harm have been included. The proposed finding should ordinarily be included in the final EIS or negative declaration for the proposal.

8. Applicability.

a. All programs and projects proposed for direct construction, assistance, or permit by the DOT shall be reviewed for consistency with the policy of this order.

b. This order does not apply to projects presently under construction or to projects for which all funds have been obligated through fiscal year 1977, to projects and programs for which a draft or final EIS was filed prior to October 1, 1977.

c. Nothing in this order shall apply to assistance provided for emergency work essential to save lives and protect property or public and safety, performed pursuant to sections 305 and 306 of the Disaster Relief Act of 1974 or pursuant to other emergency operations.

ALAN BUTCHMAN,
The Deputy Secretary.

ATTACHMENT 1

Further information concerning the type, number, and location of wetland areas may be obtained from Circular No. 39 of the Department of the Interior, Fish and Wildlife Service, or from the wetlands inventories maintained by the various States. The classification system presently contained in Circular No. 39 is being revised to provide uniformity in concept and terminology throughout the United States. A notice of intent to adopt the classification system was published in the December 12, 1977, FEDERAL REGISTER. Copies of the new classification system may be obtained from the Fish and Wildlife Service, Suite 217, Dade Building, 9620 Executive Center Drive, St. Petersburg, Fla. 33702.

The Fish and Wildlife Service is also developing a national wetlands inventory maps which will be complete in 1981. They will display typical wetland information on U.S. Geological Survey base maps for all of the States and U.S. territories and possessions. Maps are currently available to coastal Texas and Louisiana. On new projects, Fish and Service should be contacted to determined whether maps have been developed.

[FR Doc. 78-27723 Filed 9-28-78; 8:45 am]

Federal Register

FRIDAY, SEPTEMBER 29, 1978
PART VII

DEPARTMENT OF COMMERCE

Office of the Secretary

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NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Proposed Criteria for Accrediting Testing Laboratories That Test Thermal Insulation Materials

[3510-13]

DEPARTMENT OF COMMERCE

Office of the Secretary

NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Proposed Criteria for Accrediting Testing Laboratories That Test Thermal Insulation Materials

AGENCY: Assistant Secretary of Commerce for Science and Technology.

ACTION: Notice of proposed criteria to be used by the Department of Commerce for accrediting laboratories that test thermal insulation materials.

SUMMARY: Pursuant to the procedures for a National Voluntary Laboratory Accreditation Program (NVLAP) (15 CFR Part 7) this notice gives the text of the proposed general and specific criteria to be used by the Secretary of Commerce (Secretary) in accrediting testing laboratories that voluntarily request such accreditation. These proposed criteria are based on the recommendations of the National Laboratory Accreditation Criteria Committee for Thermal Insulation Materials (Committee) submitted to the Secretary on August 3, 1978. These recommendations were developed by the 21-member Committee during three meetings on May 22-23, June 29-30, and July 25-26, 1978. The procedure to be used by the National Bureau of Standards (NBS) in examining the laboratories requesting accreditation was described during these meetings. Although such procedure is not an integral part of the criteria, knowledge of it is pertinent to an understanding of the scope of the criteria.

The procedure for accrediting a testing laboratory testing thermal insulation materials will begin when the laboratory formally requests such accreditation of the Secretary. A detailed questionnaire, based on the final laboratory accreditation criteria, will then be sent to the laboratory for completion. The accreditation procedure will include three separate evaluations. First will be an evaluation of the completed written questionnaire submitted by the laboratory. When this evaluation is completed, an on-site visit by NVLAP inspectors will be arranged in which the information submitted will be verified and a comparison will be made between the laboratory's capabilities and the requirements of the test methods and the criteria. Finally, the laboratory will be required to participate in proficiency sample testing programs, and test data submitted to NBS upon completion of these programs will be evaluated. The decision to accredit a testing laboratory will be based upon all three of these evaluations.

The criteria proposed herein, as may be amended upon consideration of public comment, will form the basis for examination of the laboratory. Each criterion presented in this notice is followed by a note, summarizing the factors to be used in evaluating the laboratories. These notes are explanatory and are not part of the criterion. The substantive issues section in this notice describes some of the factors considered by the Committee in arriving at its recommendations.

This proposal substantively deviates from the Committee's recommendations in only five sections. In sections G2.1.4 and G3.2.3, the Secretary has broadened and added language to include consideration of how a laboratory handles all complaints, including complaints from the public, rather than just complaints from its clients. In sections G2.3 and S1.2, parenthetical material has been added to provide examples intended to clarify the meaning of those provisions. In section S2.2, material has been added to assure adequate concern for the accuracy of test equipment.

DATES: Written comments are due on or before November 13, 1978. A request for an informal public hearing may be made before October 16, 1978.

FOR FURTHER INFORMATION CONTACT:

Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230, 202-377-3221.

SUPPLEMENTARY INFORMATION: In a notice published in the FEDERAL REGISTER on February 25, 1976 (41 FR 8163-8168), the Department of Commerce issued procedures (15 CFR Part 7) for the operation of a National Voluntary Laboratory Accreditation Program (NVLAP). As announced in that notice, the goal of the program is to provide a national voluntary system to examine, upon request, the professional and technical competence of private and public testing laboratories. The procedures guide the development of accreditation criteria, such as those proposed in this notice, for evaluating laboratories which serve regulatory and nonregulatory product evaluation and certification needs. As criteria are developed and issued, the Secretary will accredit those laboratories which meet the criteria. In the Department Organization Order 10-1, Amendment 1, dated June 4, 1976, the Secretary has delegated to the Assistant Secretary for Science and Technology (Assistant Secretary) the authorities to exercise the pertinent functions of the Secretary in carrying out NVLAP as described in the procedures.

Pursuant to the referenced procedures, the Thermal Insulation Manufacturers Association, Inc., Mount Kisco, N.Y.; the National Mineral Wool Insulation Association, Inc., Summit, N.J.; and the Cellulose Insulation Manufacturers Association, Inc., Elk Grove Village, Ill., filed with the Secretary of Commere on December 1, 1976, a joint request that the Secretary find that there is a need to accredit testing laboratories which render services in the field of thermal insulation.

In a notice published in the FEDERAL REGISTER on October 12, 1977 (42 FR 55020-55023), the Department announced a final finding of need to accredit testing laboratories that test thermal insulation materials using the standards and test methods identified in the notice. In a separate notice published simultaneously in the FEDERAL REGISTER (42 FR 55023-24) the Department announced the formation of a National Laboratory Accreditation Criteria Committee (Committee) of 21 members to develop criteria to be used to evaluate those laboratories. Committee members were appointed in April 1978, met in May, June, and July for 2 days at each of the three sessions, and recommended criteria to the Assistant Secretary on August 3, 1978. Those recommendations provide the basis for this FEDERAL REGISTER Notice.

The Secretary will accredit a testing laboratory upon request, on the basis of an evaluation by NBS of the laboratory's ability to meet the provisions of the final criteria. The final criteria will be based on these proposed criteria with appropriate changes made after careful consideration and evaluation of all public comments received as a result of this notice. The final criteria published in the FEDERAL REGISTER will contain specific instructions for making application for accreditation by testing laboratories which test thermal insulation materials.

Upon receipt of a request for accreditation from a testing laboratory, the Assistant Secretary shall acknowledge the request and ask NBS to send an application package to the laboratory. This package will describe the accreditation program and will help the requesting laboratory select those portions of the program in which it specifically seeks accreditation. The application, when returned to NBS, will be used in assembling a questionnaire package, based upon the final criteria and the specific standards and test methods for which the laboratory desires accreditation. This questionnaire, tailored to the needs of the requesting laboratory, will elicit specific information about its qualifications and capabilities.

In completing the questionnaire for the test methods of interest, a labora-

tory may find that a duplication of information is needed in several portions of the questionnaire. Such duplication is not required. For instance, if information is contained in the response to the general criteria, identical information need not be supplied in response to the specific criteria. Likewise, information supplied in response to specific criteria for one test method need not be supplied in response to specific criteria for another test method if such information is identical.

Upon receipt of the completed questionnaire, NBS will evaluate the laboratory's ability to meet the criteria which apply to the areas in which the laboratory desires accreditation. In conducting this evaluation, the evaluators will reference specific detailed requirements for each of the test methods (e.g. test instruments required, reference documents cited, standardization equipment called for, and any special facilities called for) and will compare the data submitted by the laboratory with these requirements. A listing of these requirements as stated in each test method is now being developed and copies of the supplemental listing pertaining to each test method for which accreditation is sought will be supplied to the laboratory along with the questionnaire. Consultation with the laboratory will be arranged, if necessary, to complete the questionnaire.

Upon successful completion of this evaluation, NBS will then schedule an on-site visit by a NVLAP inspector whose inspection will include verification of the information submitted and comparison of the laboratory's capabilities and the requirements of the test methods and criteria. In conducting the inspection, the inspectors will reference specific detailed requirements for each of the test methods and each criterion and will compare the laboratory's capabilities with these requirements. A listing of these requirements as stated in each test method is now being developed and copies of inspector verification forms pertaining to each test method for which accreditation is sought will be supplied to the laboratory along with the questionnaire.

NBS will also schedule all required participation of the laboratory in proficiency testing programs as required. The questionnaire, inspector's report, and proficiency test data will then be evaluated by NBS and their recommendation concerning accreditation will be made to the Assistant Secretary. After review by the Assistant Secretary, accreditation will be granted or a letter denying accreditation will be sent to the laboratory.

To be accredited, the laboratory must also pay accreditation fees and charges. A schedule of estimated fees and charges the Department proposes to establish is published simultaneously in a separate notice in this FEDERAL REGISTER issue as required by the NVLAP procedures. These fees and charges are in amounts calculated to cover the costs of NVLAP examinations and are furnished at this time for information and guidance purposes only in order that the public may evaluate the proposed criteria in light of the expected fees to be charged for the assessment and accreditation of interested laboratories based upon those criteria.

To be accredited, the testing laboratory must agree to be examined and audited initially and on a continuing basis. During the deliberations of the Committee, an interval between examination for accreditation and reexamination for reaccreditation of 2 years was suggested as nominal based on the experience in other laboratory evaluation programs. The Committee has strongly recommended that testing laboratories be inspected on a yearly basis. The Department has carefully weighed this recommendation in light of the following factors: (a) inspection costs constitute a substantial portion of the total costs of examination and it is believed that annual inspection may increase the fee to unduly burdensome levels for a number of laboratories; (b) it is recognized that inspections may cause a significant (albeit temporary) disruption in the business of the laboratory and as such should be no more frequent than absolutely necessary; (c) other mechanisms exist by which to determine any deterioration in the competence of the laboratory between inspections; and (d) the Secretary reserves the right to call for inspections of laboratories at any time between regular inspections for the purpose of insuring continued compliance with the criteria. Until operating experience suggests a need to do otherwise, it is proposed to call for the regular examination (including inspection) of a laboratory at an interval of 2 years plus or minus 3 months. This tolerance of plus or minus 3 months is in recognition of practical problems of scheduling a series of inspections in different parts of the country. Public comments on this issue are encouraged.

Finally, to be accredited, the testing laboratory must avoid reference by itself and forbid others utilizing its services from referencing its accredited status in consumer media and product advertising, or on product labels, containers, or packages or the contents therein. This provision was included in the basic NVLAP procedures because the attributes of a product depend not only on whether the laboratory that tests it is accredited for that test method, but also on a number of other factors including the frequency of such tests, and the manner in which the manufacturer uses the test results to control the quality with which the product is manufactured. A laboratory may indicate on its letterhead and in professional, technical, and trade publications that it has been accredited by the Department to test products using a specific test method. Moreover, the Department will publish a list of accredited laboratories in the FEDERAL REGISTER so that the facts of such accreditation are available to users of testing laboratory services.

SUBSTANTIVE ISSUES

During the development of the criteria which were recommended to the Secretary by the Committee, a number of substantive issues were discussed in detail. These discussions are summarized in the following paragraphs in order to provide background information for the reader of this notice.

ORGANIZATIONAL STRUCTURE OF THE LABORATORY

Several members of the Committee strongly advocated that only independent laboratories be accredited. Such a provision is prohibited by the NVLAP procedures. (15 CFR 7.7(e)(1).) "No action will be taken or criteria developed that would prohibit the accreditation of a testing laboratory solely on the basis of that laboratory's association or nonassociation with manufacturing, distributing, or vending organizations * * *"). It was also pointed out that a definition of "independent" was itself subject to interpretation and challenge. (Is a laboratory truly independent if it performs 25 percent of its work for one client? 50 percent? What happens when a laboratory becomes part of a conglomerate organization?) There also seemed to be some confusion between laboratory accreditation and product certification. Accreditation of a laboratory means that the laboratory has the capability to conduct the specified tests appropriately. Certification of a product indicates that the product meets the requirements of a standard using designated product tests. NVLAP deals only with laboratory accreditation. NVLAP procedures specifically forbid reference to an accredited laboratory in product advertising, or in product labels, containers, and packaging or the contents therein, to avoid any inference of product certification.

The Committee explored the idea of requiring the names and resumes of all management and supervisory personnel in each operating, support, and service unit of the laboratory. To many members of the Committee this seemed like an excessive documenta-

tion burden—particularly for some of the larger laboratories. This was particularly so when considering section G4.1 of the criteria which requires an update of such information within 30 days of the occurrence of any substantive changes in the laboratory related to these criteria. The Committee voted to accept an amendment which calls for the names and resumes or the personnel requirements only for the positions identified. However, the Department believes that it may be necessary to know the names and actual qualifications of the persons filling key positions since, if a key person should leave a laboratory and not be replaced by another qualified person, the continued capability of the laboratory could be in serious doubt. Some people who choose a NVLAP accredited laboratory may do so because of its accreditation by the Department. Any material change in a basis for the accredited status must be evaluated by the Department promptly so that if that status deserves to be changed, the public may be notified of that fact in timely fashion. In order to meet the Committee's concern regarding paperwork, yet provide what could be critical information, it may be appropriate to require names and resumes (which need not exceed one page) of individuals that are key to the operation of a testing laboratory (e.g., the laboratory director or manager and those key supervisors in the area for which accreditation is sought). Public comments on this issue are encouraged.

The committee rejected a proposed criterion which would have required a laboratory to describe its sources and manner of financial support or other evidence of financial stablity. Proponents of this provision argued that such a provision was needed to evaluate a laboratory's ability to develop and manage testing programs on a continuing basis. One member of the committee so strongly favored this provision that he submitted a minority comment to the Secretary with the final recommeded criteria stating, that in his opinion, there would be a high risk that a labortory in an unstable financial condition might not maintain quality performance in its laboratory practices. Opponents of this position argued that it would be very unfair to new and developing laboratories, and almost impossible to evaluate appropriately. Also to be considered is the provision in the NVLAP procedures (15 CFR 7.7(e)(5)) that the Secretary will not ask for or accept confidential business data, trade secrets, or other proprietary information.

PROFESSIONAL AND ETHICAL BUSINESS PRACTICES

Under this heading, the committee discussed factors including: the handling of complaints; protection of test data, records and reports; and limitation of work in accordance with demonstrated capacities and competences. The issues of independence arose again and was resolved by requiring the laboratory to supply evidence that there is an independent decisional relationship between the testing laboratory function and other functions of the company or from other organization with which the laboratory does business.

The only area of substantial deviation from the criteria recommeded by the committee is in the area of complaint handling. The department is of the view that it is vitally important for the laboratory to handle appropriately all complaints. In order to accomplish this, a new section, G2.1.4, was added to criterion G2 dealing with the quality control system. This section would require that the laboratory describe its procedures for obtaining, tracing the validity of, and responding to complaints and charges about the quality of test work. To further support this important point, the committee's recommendation for section 3.2.3 of criterion G3 dealing with professional and business practices was modified by deleting the words "from clients." In effect, this deletion broadens that provision and requires documentary evidence that the laboratory considers and properly handles all appeals and complaints, irrespective of whether such complaints come from clients or the public.

The Committee considered requiring that the laboratory provide complete details of any litigation in which an applicant laboratory may have been involved over the past 5 years. A majority of the Committee agreed to delete such a requirement on the basis that: (1) in an ongoing suit a laboratory should be judged free of wrongdoing until shown otherwise, as required by our system of jurisprudence; (2) if a laboratory has been found guilty, or a judgment entered against it for wrongdoing, presumably it will be forced to pay for its mistakes as a result; and (3) the volume of paperwork could be enormous. Committee members favoring such a provision suggested that it would be inappropriate to accredit a laboratory which has a number of adverse judgments against it. The Department believes that conditions which lead to such litigation are likely to show up during the evaluation. In any event, the Secretary is prepared to followup on complaints received from the public about any laboratory accredited or about to be accredited.

NOTIFICATION OF CHANGES.

The Committee agreed after some discussion that the laboratory should notify NVLAP of substantive changes in the laboratory related to the criteria requirements on a timely basis, even though for a large facility this could involve substantial paperwork.

The NVLAP program is designed to adapt to changes in the cited standards and test methods as they are approved ability to designate some other effective date if deemed necessary.

LABORATORY FACILITIES AND EQUIPMENT.

Some test methods define required facilities, equipment, and special features very explicitly while other test methods do not. In some test methods, equipment has to be fabricated and constructed on site using general design guidance. The degree of conformance of the facilities and equipment to the requirements of the test methods is also a significant issue. In its deliberations, the Committee stressed the need to relate facilities and equipment to calibration and verification requirements to assure accurate and precise data.

A major discussion centered on the use of equipment, facilities, or procedures which have received modifications that keep them from being in strict conformance to the test method but which are judged to be noncritical modifications. Some Committee members encouraged such modifications, arguing that improvements which reduce costs or improve accuracy of measurements should be allowed and perhaps openly encouraged. The Department supports this goal, and therefore modified criterion S2.2 to encourage concern that equipment provide requisite accuracy and precision.

During the discussion of improvements and modifications some Committee members indicated a need to retain the pure methodology of the test method. The Committee therefore recommended the allowance of noncritical modifications provided the testing laboratory which is being accredited demonstrates appropriately through comparative analysis that such modifications do not degrade the precision or accuracy of the data obtained in using the test method.

In reviewing this recommendation, the Department concluded that criterion S2 might not provide necessary encouragement to modernization especially on new tests and methods undergoing significant development. The Department notes that criterion S1 encourages attention to training of personnel to assure continuous proficiency. The question of whether similar encouragement is needed on the currency of equipment with advances in technology remains open. Such encouragement could be added in an additional subsection dealing with and calling for a review of the laboratories' efforts to maintain knowledge of ad-

vancing technology through such means as professional literature, trade and professional meetings, seminars, and professional education, etc. Public comments on these issues are invited.

The Committee also addressed issues associated with the use of subcontractors. It was agreed that in many cases it is not uncommon for even the most accomplished laboratories to employ specialists to perform some specific functions such as preparation of samples, preliminary assessments, or computer and statistical analysis. It was agreed that only a testing laboratory having the measuring facilities and equipment to produce the final test values could be accredited for the test for which accreditation is sought. When subcontracting is performed to obtain test specimens or intermediate values, the testing laboratory producing the final test values would be responsible for the work of the subcontractor. Subcontractors need not be accredited for the test method or for that portion of the test method they conduct in order for accreditation to be granted to the primary testing laboratory.

The Proposed Criteria

Compliance by testing laboratories with these general and specific criteria and accreditation of a laboratory by the Secretary shall in no way relieve such laboratory from the necessity of observing and being in compliance with existing Federal, State and local statues, ordinances, and regulations that may be applicable to the operation of such laboratory, including consumer protection and anti-trust laws.

GENERAL CRITERIA

For initial accreditation or continued accreditation, an applicant laboratory shall provide the information listed below for the general product and testing areas for which accreditation is sought.

A single or double asterik preceding a section number identifies section to be included in quality control procedures as explained in section G2.6.

Criterion G1. *The laboratory has an organizational structure that enables it to develop and maintain a testing capability to perform satisfactorily the functions for which accreditation is sought.*

G1.1 A description of the laboratory's organization, including:

*G1.1.1 The complete legal name and address of the main office, or parent company if part of a larger organization;

*G1.1.2 The name and location of the laboratory if different from that stated in G1.1.1;

G1.1.3 A general description of the laboratory, including its equipment and facilities;

G1.1.4 The laboratory's and parent company's principal ownership and management structure, including the names and positions of the principal officers and board of directors;

*G1.1.5 An outline or chart showing the titles or positions of all key management and supervisory personnel in each operating, support, and service unit in the laboratory's functional organization, and their reporting relationships relative to this accreditation request;

**G1.1.6 The names and resumes of the individuals assigned to each of the positions identified in G1.1.5 or the personnel requirements for the individuals occupying those positions.

G1.2 A listing of the relevant technical services performed.

*G1.3 A list of test method standards for which accreditation is sought, showing the approximate number of times each test is performed per year.

NOTE.—This criterion and its sections require a relatively straightforward description of the testing laboratory. The examiner will review data supplied by the laboratory in response to this criterion for appropriate definition of authority and responsibility, for the personnel qualifications, and for consistency between services offered and personnel and facilities available. The inspector will verify data on the facility and organization, and personnel, and conduct appropriately related examinations:

Criterion G2. *The laboratory has and maintains a quality control system to assure the technical integrity of its work.*

**G2.1 A description of the laboratory's system for auditing and monitoring its test work, including procedures for:

G2.1.1 Preventing or reducing testing errors and discrepancies;

G2.1.2 Identifying and correcting known errors and discrepancies;

G2.1.3 Specifying the frequency and the sample size (quantity) of the audit sampling of the test results of testing personnel.

G2.1.4 Obtaining, tracing the validity of, and responding to complaints and charges about the quality of test work.

**G2.2 A description of the laboratory's system for insuring that all test equipment and reference standards are calibrated or verified to the requisite degree of accuracy, including procedures for:

G2.2.1 Maintaining written descriptions of the standardization (calibration and verification) procedures for all test equipment and reference standards;

G2.2.2 Maintaining standardization records, including:

(a) Equipment description or name,

(b) Name of manufacturer,

(c) Model, style, and serial number or other identification,

(d) Equipment variables subject to standardization,

(e) Range of operation and range of standardization,

(f) Resolution of the instrument and allowable error tolerances on readings,

(g) Standardization schedule (intervals),

(h) Date and result of last standardization and date of next standardization,

(i) Name of laboratory person or standardization service providing the above standardization,

(j) Traceability to NBS or other authority as required;

G2.2.3 Insuring that all test equipment is recalled periodically for verification and/or recalibration.

**G2.3 A description of the laboratory's system for assuring that all equipment and facilities are properly maintained (e.g., routine operational checks and upkeep, maintenance of instructions for equipment operation and repair, power sources, electricity, and gases).

**G2.4 A description of the laboratory's system for controlling the flow of work, including procedures for at least the following:

G2.4.1 Specifying work flowfrom reception to reporting;

G2.4.2 Specifying the functions to be performed at each step along the workflow path;

G2.4.3 Data recording, processing and reporting;

G2.4.4 Selecting specimens for testing;

G2.4.5 Retention or disposal of specimens tested.

**G2.5 A description of the laboratory's system for maintaining records, including records of:

G2.5.1 Test reports;

G2.5.2 Data generated during testing;

G2.5.3 Receiving, shipping and disposal of test samples;

G2.5.4 Current regulations, test standards and specifications;

G2.5.5 Personnel (including training);

G2.5.6 Appeals actions contesting results.

G2.6. A copy of the laboratory's quality control manual or procedures which should:

G2.6.1 Explicitly include the information required by the single starred (*) sections of these general and specific criteria;

G2.6.2 Clearly state where in the laboratory this information is maintained or explicitly include the information required by the double starred (**) sections of these general and specific criteria.

*G2.6.3 Explicitly include the procedures to be followed for maintaining the manual current and the name or title of the person responsible for implementing those procedures.

NOTE.—In assessing a laboratory's capability to meet this criterion, the examiners, based on data submitted by the laboratory, will be making judgments about the adequacy of the test auditing and monitoring program of the laboratory, about the adequacy of the laboratory's calibration system, about the appropriateness of the laboratory's equipment and facility maintenance, about the laboratory's system for controlling the flow of work, and about the laboratory's system for maintaining records. The inspector will verify the data supplied and examine the laboratory for related information.

The laboratory's quality control system must be documented, by a quality control manual or written procedures. The purpose of the manual is to provide, in one convenient location, detailed descriptions, or clear instructions where such descriptions may be found, of the operating and quality assurance procedures governing the human and material resources of the laboratory. The manual must be available at all times to serve as a guide for the laboratory staff, and procedures must exist for maintaining and periodically updating it. It is subject to review during on-site laboratory inspections by NVLAP personnel. An example of how such a manual might be structured is presented in the American Council of Independent Laboratories (ACIL) publication, *Quality Control, Requirements for a Testing and Inspection Laboratory, Manual of Practice—1976.* As a minimum, the manual should be structured in accordance with sections G2.6.1, G2.6.2, and G2.6.3 above.

Criterion G3. *The laboratory is operated in accordance with generally accepted professional and ethical business practices.*

G3.1 The laboratory has a stated and effective policy which assures that reported values accurately reflect all properly measured data.

G3.2 Documentary evidence assuring that:

G3.2.1 Test work is limited to that for which competence and capacity are available;

G3.2.2 Test data, records, and reports are treated as proprietary information and are released only to such other individuals as the client agrees to in writing;

G3.2.3 Appeals and complaints contesting test results are considered and properly handled.

G.3.3 For a laboratory that is part of a larger organization, dependent on manufacturing or supplier interest: evidence that there is an independent decisional relationship between the testing and other components of the organization. (This may be demonstrated, for example, by a letter of authority from the parent organization management.)

G3.4 For a private laboratory that is not part of a larger manufacturing or supplier organization: Evidence that there is an independent decisional relationship between the laboratory and other organizations, including clients (e.g., a policy declaration or a contract provision that the laboratory's relationship with these organizations are not allowed to affect the laboratory's capacity to render reports of findings objectively and without bias).

NOTE.—The examiners will review data supplied by the laboratory and compare them with other data provided under criteria G1 and G2 to evaluate compliance with this criterion. Particular attention will be paid under this criterion relative to complaints received about the laboratory by the Assistant Secretary. The inspectors will verify data provided and explore with the laboratory personnel individual complaints which may have arisen.

Criterion G4. *During the processing of the application and following accreditation, the laboratory reports to NBS, within specified times, any substantive changes in the laboratory related to the general and specific criteria, and documents these changes as per the original submission.*

G4.1 A description of the change mailed within 30 days following a substantive change relative to the general and specific criteria.

G4.2 Implementation within 45 days of the effective or "official notice" date, whichever is later, of all changes necessitated by a revision in the standard test method, unless another date is established by notice from NBS. (The "official notice" date is the date the organization responsible for the standard test method gives notice in its official publication that the standard has been revised. In some cases the organization may indicate a later "effective" date.)

NOTE.—The examiners will evaluate changes as they may affect other aspects of the criterion and the inspectors will report absence of unreported substantive changes.

SPECIFIC CRITERIA

For *each standard test method* for which accreditation or continued accreditation is sought, an applicatant laboratory shall provide the information required.

Criterion S1. *The laboratory is staffed with trained and experienced personnel competent in the principles and practices of measurement in the area of testing for which accreditation is sought.*

**S1.1 A list of, or the requirements of, the personnel responsible for and capable of conducting the tests specified in the test method, if not specifically addressed in the response to section G1.1.6 of the general criteria.

**S1.2 A description of the specific training program to assure proficiency and uniformity in applying the test method to the requisite degree of accuracy and precision (e.g., methods for ensuring job competence, probationary periods under close supervision, audits of test work performed, and performance reviews with affected personnel).

NOTE.—For each test method for which a laboratory requests accreditation, the examiner will evaluate the competence of the personnel function and the training function. Of concern also would be how personnel newly trained moved into the work force, the nature of periodic reviews of competence, and the kinds of continuous education programs available. The inspector would verify the content and utilization of training programs and as a result of observations made to assess compliance with other specific criteria, would attest to the competence of the personnel.

Criterion S2. *The laboratory's facilities and equipment are appropriate to the functions for which accreditation is sought and are properly maintained.*

**S2.1 A description of the test setups and a list of test instruments used, sufficiently identified to allow correlation with the calibration information requested in criterion S3. (Provide diagrams and photographs, if helpful in demonstrating conformance with the test requirements.)

**S2.2 A description of all special or laboratory-fabricated equipment listed in section S2.1, and evidence that this equipment conforms to the requirements of the test method and assures requisite accuracy and precision. (Provide schematics or shop drawings with annotated photographs, if helpful in demonstrating conformance with the test requirements.)

**S2.3 A description of any auxiliary equipment, facilities, or procedures required by or used for the test method, such as: storage and conditioning of samples; environmental conditions or controls (including how compliance is measured and percentage of time within required limits); automatic data collection, reduction or analysis; housekeeping, safety and custodial care; maintenance of laboratory equipment and facilities.

**S2.4 An inventory of the laboratory's collection of applicable standards and other documents referred to or used for the test method.

**S2.5 Evidence by analytical or other means that the test results are not degraded by the use of equipment or facilities which have received non-critical modifications not in strict conformance with the standard method of test.

NOTE.—For this criterion, the examiner would evaluate the set-ups, instrumentation, special equipment, facilities, etc. of the laboratory as compared to the requirements

of each test method for which accreditation is sought. Evidence would be evaluated to confirm that non-critical modifications have not degraded the test results. The inspector would explore evidence justifying claims made by the laboratory during his visit to the laboratory by comparing selected measurements with the requirement of the test methods.

Criterion S3. *The laboratory's equipment and procedures are standardized (calibrated and verified) periodically.*

**S3.1 A description of the standardization equipment (including diagrams, etc., as appropriate) and a listing of the standardization schedule to ensure continuing adequate performance and accuracy of results.

**S3.2 Either references to recognized standardization procedures or descriptions of standardization procedures used for each laboratory standard and test instrument to assure that all measurements can be made to the requisite precision and accuracy.

**S3.3 A listing of the reference standards and materials being used with the test method, including:

S3.3.1 The source, the identify and latest dates and results of the standardization of the reference standards and materials;

S3.3.2 For other than specifically required standards and standard reference materials, the procedures used to reference the standards to national standards;

S3.3.3 Clear identification and differentiation between reference and working standards.

**S3.4 A listing of the measurement assurance, collaborative reference or other program(s), appropriate to the test method, in which the laboratory participates.

NOTE.—This criterion relates to the laboratory's fundamental program for establishing and maintaining basic references upon which its testing program is built. In some cases, much of the standardization procedures required herein will be part of an overall computerized laboratory program. In other cases, such standardization will be accomplished on a test method by test method basis. The examiners and inspectors will be responsive to evaluation and verification in either case.

Criterion S4. *The laboratory maintains documented and acceptable in-house operating protocols for the test method to assure the requisite degree of accuracy and precision.*

**S4.1 A copy of the in-house instructions, if any, supplementing the instructions of the standard test method, including those necessary for equipment maintenance and calibration checks, sample preparation, testing and disposal, data reduction, and reporting of test results.

**S4.2 A copy of the instructions to the subcontractor, and a description of how the laboratory assures the required precision and accuracy for any highly specialized part of the test method which is subcontracted.

NOTE.—Only that laboratory having the measuring equipment by which final test values are obtained can be accredited.

**S4.3 Evidence by analytical or other means that the use of non-critical variations in the procedure from that specified in the standard test method does not degrade the results of the test.

**S4.4 Evidence demonstrating the capability of satisfactorily complying with the intent of the standard test method when any variation in test equipment or procedures is made necessary by environmental conditions or by special requirements of a product for which accreditation is sought.

**S4.5 A sample test report (with name of client deleted) showing test results accompanied by the raw data and a copy of the worksheet showing the steps to reduce the raw data and the method of data reduction or reference to approprate "calculation" sections of the test protocol or standard.

NOTE.—This criterion deals with the fundamental ability of the laboratory to obtain test results to the required precision and accuracy of the test methods. When reviewing data submitted by the laboratory, the examiner's emphasis will be placed upon evaluation of instructions and procedures for the staff of the laboratory and for any subcontracted segments of the work. The applicability of nonconforming test procedures will also be carefully evaluated. A sample report will be reviewed and the inspectors will look for evidence that such sample reports are typical rather than specially produced for the accreditation program.

REQUEST FOR COMMENTS

Interested persons desiring to comment on the proposed criteria set out above are invited to submit such comments, in four copies, on or before November 13, 1978, to the Assistant Secretary for Science and Technology, Department of Commerce, Room 3864, Main Commerce Building, Washington, D.C. 20230.

Any person desiring to express his or her views in an informal hearing relative to the mentioned proposed criteria shall do so by communicating that desire in writing on or before October 16, 1978, to the Assistant Secretary for Science and Technology at the address shown in the preceding paragraph. Upon receipt of such request, informal public hearings will be held so as to give all interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to the opportunity to make written submissions. If deemed appropriate, such hearings may be held at two locations, one of which shall be east of the Mississippi River and the other west thereof. Notice of such hearings will be published in the FEDERAL REGISTER at least twenty (20) days in advance thereof. A transcript will be made of any oral presentation.

PROCEDURE FOLLOWING RECEIPT OF COMMENTS

Upon receipt of all written and oral comments, the Criteria Committee will be requested to conduct and return to the Assistant Secretary, within a specified time, its evaluation and recommendations with respect to such comments. After considering the Criteria Committee's evaluation and recommendations, the Assistant Secretary will prepare his evaluation and publish in the FEDERAL REGISTER a notice:

(1) Announcing the final general and specific criteria that testing laboratories must meet in order to be accredited and the date when such final criteria shall go into effect which shall not be less than thirty (30) days after the date of publication of such notice;

(2) Stating that the proposed general and specific criteria will be further developed before final publication; or

(3) Withdrawing the proposed general and specific criteria from further consideration.

RELATED INFORMATION

A list of test methods which will be included in this program, along with a statement of the requisite precision and accuracy of each method and an indication of the requisite reference programs is set out in appendix 1. Further research may require that the values for the requisite precision and accuracy or participation in requisite reference programs change during the course of the program. When such changes are developed, they will be published and made effective immediately on publication. Specific information on each test method will be supplied in the questionnaire booklet to a laboratory requesting accreditation.

Although the data presented in appendix 1 are considered part of the operational material of the program and are not part of the criteria, comments from the public are nonetheless solicited at this time, especially as related to the requisite precision and accuracy of those data.

All written and oral comments and testimony that are furnished in response to the invitation made by this notice will be made part of the public record and will be available for inspection and copying in the Department's Central Reference and Records Inspection Facility, Room 5317, Main Commerce Building, 14th Street between E Street and Constitution Avenue NW., Washington, D.C. 20230.

Dated: September 26, 1978.

JORDAN J. BARUCH,
Assistant Secretary for Science and Technology.

APPENDIX 1. U.S. DEPARTMENT OF COMMERCE NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM (NVLAP)

PROPOSED CRITERIA AND COMPLIANCE INFORMATION SUPPLEMENT FOR THERMAL INSULATION MATERIALS

This table establishes the performance requirements for the initial and continued accreditation of laboratories that test thermal insulation materials. It also specifies the available reference and related programs that help assure that performance.

The performance requirements are specified in terms of the requisite precision and accuracy in applying the test method; that is, the overall precision and accuracy of application involving such potential sources of error as test operator, test environment, test equipment, test protocol and test sample. The capability of a laboratory to perform to these overall requirements is judged from the written information it submits in response to the examination material and from the findings of the on-site inspection. The ability of the laboratory to apply this capability is determined from the results of its performance in a proficiency testing program.

Precision is expressed in terms of repeatability (R) and comparability (C). Repeatability is a measure of the ability of a laboratory to repeat its own test result on the same or essentially identical samples. Comparability is a measure of the ability of a laboratory to compare two materials (intended for the same use), obtaining comparative test results (e.g. difference between or ratio of the two test results) consistent with comparisons obtained by other laboratories. Accuracy (A), is a measure of the ability of a laboratory to obtain a test result in agreement with the "true" or target test result.

The limits specified in the table for precision and accuracy are for "good" performance. Approximately 95 percent of the laboratories should be able to achieve this. Limits approximately 50 percent wider are used to define "acceptable" performance for accreditation purposes. CAUTION: The limits presented in this table for laboratory accreditation purposes should not be interpreted as setting specification limits on products.

In addition to utilizing or participating in the requisite reference programs listed below for each test method, each laboratory should maintain a uniform batch of test specimens for more frequent checks of its performance (or should use other means for this purpose). The sources for the requisite reference programs are listed at the end of the table. The table shows those programs currently available. As other programs become available, especially for methods not now covered, and are determined to be desirable for NVLAP, they will be added to the table.

NVLAP Code Test Method No.	Complexity	Short title (property) subtitle (if applicable)	Requisite precision and accuracy	Requisite reference program(s)
01/D01—ASTM C136	B,[1]	Sieve or screen analysis	R=4 pct aggregate—A=4.4 pct aggregate.	SRM's 1017a,[2] 1018a, 1019a or NBS sieve verification service.[2]
01/D02—ASTM C167	B,	Thickness and density; blanket and batt	Thickness: A=1/16 in. (1.0 mm). Density: A=2 pct.	
01/D03—ASTM C209 (par. 6 in 72 version).	B,	Thickness; board (cellulosic fiber)	A=0.1 mm	
01/D04—ASTM C209 (par. 13 in 72 version).	B,	Water absorption, 2 h; board (cellulosic fiber).	A=25 pct water absorption	TIM CRP.[4,5]
01/D05—ASTM C209 by D1037 (par. 100-106 in 72 version).	B,	Water absorption, 24 h; board (cellulosic fiber).	do	TIM CRP.[5]
01/D06—ASTM C209 by D1037 (par. 107-110 in 72 version).	B,	Linear expansion; board (cellulosic fiber)	A=0.1 pct expansion	
01/D07—ASTM C272	B,	Water absorption; core materials	A=25 pct water absorption	TIM CRP.[5]
01/D08—ASTM C302	B,	Density; preformed pipe insulation	Thickness: A=1 mm. Density A=2 pct.	
01/D09—ASTM C303	B,	Density; preformed block insulation	A=2 pct	
01/D10—ASTM C355	B,	Water vapor transmission; thick materials; desiccant method.	A=25 pct	TIM CRP.
01/D11—ASTM C356	B,	Linear shrinkage; soaking heat; preformed high temperature insulation.	R=0.5 pct linear shrinkage; A=0.5 pct linear shrinkage.	
01/D12—ASTM C411	B,	Hot-surface performance; high temperature insulation.	Warpage: A=1 mm	
01/D13—ASTM C519	B,	Density; loose-fill (fibrous)	A=2 pct	
01/D14—ASTM C520	B,	Density; granular loose-fill	A=2 pct	
01/D15—ASTM D756	B,	Weight and shape changes; accelerate service (proc. A); plastics.	A=0.5 pct weight change; A=0.5 pct linear dimension change; A=1.5 pct volume change.	
01/D16—ASTM D756	B,	Weight and shape changes; accelerated service (proc. B); plastics.	Same as for 01/D15	
01/D17—ASTM D756	B,	Weight and shape changes; accelerated service (proc. E); plastics.	do	
01/D18—ASTM D162	B,	Apparent density; rigid cellular plastics	A=4 pct	
01/D19—ASTM D2126	B,	Response to thermal and humid; aging (proc. B); rigid cellular plastics.	A=0.5 pct weight change; A=0.5 pct linear dimension change.	
01/D20—ASTM D2126	B,	Response to thermal and humid; aging (proc. D); rigid cellular plastics.	Same as 01/D19	
01/D21—ASTM D2126	B,	Response to thermal and humid; aging (proc. E); rigid cellular plastics.	do	
01/D22—ASTM D2126	B,	Response to thermal and humid; aging (proc. F); rigid cellular plastics.	do	
01/D23—ASTM D2842	B,	Water absorption; rigid cellular plastics	A=1.0 pct absorption (by volume).	TIM CRP.
01/F01—ASTM D777 as modified by Federal specification H-H-B-100B.	B,	Flammability; paper and paperboard	Char length: R=3.6 pct, A=9.0 pct; fire resistance permanence: R=6 pct increase in char length, A=10 pct increase in char length.	
01/F02—ASTM E84	B,	Surface burning characteristics; building materials; loose-fill.	Flame spread classification: A=20 pct; smoke classification: A=40 pct.	TIM CRP.
01/F03—ASTM E84	B,	Surface burning characteristics; building materials; blanket and batt.	Same as 01/F02	TIM CRP.
01/F04—ASTM E84	B,	Surface burning characteristics; building materials; board and block.	do	TIM CRP.
01/F05—ASTM E136	B,	Noncombustibility; elementary materials	Primarily a nonquantitative test.	

NVLAP Code Test Method No.	Complexity	Short title (property) subtitle (if applicable)	Requisite precision and accuracy Requisite reference program(s)	
01/S01—ASTM C165	B_2	Compressive properties; thermal insulation; proc. A.	A=4 pct	TIM CRP,[9] TMVS.
01/S02—ASTM C203	B_2	Breaking load/flexural strength; preformed block insulation.	Breaking load: A=2 pct; flexural strength: A=10 pct.	TIM CRP,[9] TMVS.
01/S03—ASTM C209 (par. 9 in 72 version).	B_2	Transverse strength; board (cellulosic fiber).	A=4 pct	TIM CRP,[9] TMVS.
01/S04—ASTM C209 (par. 10 in 72 version).	B_2	Deflection at specified load; board (cellulosic fiber).	A=0.2 mm	See 01/S03.
01/S05—ASTM C209 (par. 11 in 72 version).	B_2	Tensile strength; parallel to surface; board (cellulosic fiber).	A=15 pct	TIM CRP,[9] TMVS.
01/S06—ASTM C209 (par. 12 in 72 version).	B_2	Tensile strength; perpendicular to surface; board (cellulosic fiber).	A=4 pct	TIM CRP,[9] TMVS.
01/S07—ASTM C273	B_2	Shear test; sandwich construction	A=25 pct	TIM CRP,[9] TMVS.
01/S08—ASTM C446	B_2	Breaking load/modulus of rupture; preformed pipe insulation.	Breaking load: A=2 pct; modulus of rupture: A=5 pct.	TIM CRP,[9] TMVS.
01/S09—ASTM D781	B_2	Puncture test; paperboard and fiberboard.	R=7.3 pct; A=8 pct	
01/S10—ASTM D828	B_2	Tensile breaking strength; paper and paperboard.	R=5 pct; C=9 pct; A=11 pct	TAPPI CRP or TIM CRP.[7] [8]
01/S11—ASTM D1621	B_2	Compressive properties; rigid cellular plastics; proc. A—Crosshead.	A=6 pct	TIM CRP,[9] TMVS.
01/T01—ASTM C177	B_2	Thermal transmission properties; low-temperature guarded hot plate; loose-fill.	R=1 pct; A=4 pct	SRM 1450,[10] TIM CRP.
01/T02—ASTM C177	B_2	Thermal transmission properties; low-temperature guarded hot plate; compressible blanket and batt.	do	SRM 1450,[10] TIM CRP.
01/T03—ASTM C177	B_2	Thermal transmission properties; low-temperature guarded hot plate; rigid board and block.	do	SRM 1450,[10] TIM CRP.
01/T04—ASTM C236	B_2	Thermal conductance; guarded hot box	A=4 pct	TIM CRP.[11]
01/T05—ASTM C335	B_2	Thermal conductivity; pipe insulation	do	TIM CRP.
01/T06—ASTM C518	B_2	Thermal transmission properties; heat flow meter; blanket and batt.	R=1 pct; A=4 pct	SRM 1450,[12] TIM CRP.
01/T07—ASTM C518	B_2	Thermal transmission properties; heat flow meter, board.	do	SRM 1450,[12] TIM CRP.
01/T08—ASTM C518	B_2	Thermal transmission properties; heat flow meter; loose-fill.	do	SRM 1450,[13] TIM CRP.
01/T09[14]—ASTM C653	B_2	Thermal resistance (rec. practice); blanket (mineral fiber).	See 01/T02 and 01/T06	See 01/T02 and 01/T06.
01/T10[14]—ASTM C687	B_2	Thermal resistance (rec. practice); loose-fill (fibrous).	See 01/T01, 01/T04, and 01/T08	See 01/T01, 01/T04 and 01/T08.
01/V01—ASTM C445	B_2	Emittance of surfaces	A=0.02 emittance or 10 pct, whichever is higher.	
01/V02—ASTM D591	B_2	Starch in paper; qualitative test	Nonquantitative test	
01/V03—ASTM D2020	B_2	Mildew (fungus) resistance; paper and paperboard.	do	
01/V04—ASTM E96	B_2	Water vapor transmission—thin sheets—proc. A.	R=19 pct—A=25 pct	SRM 707-1.

[1] The letter B followed by a numerical subscript 1, 2, or 3 indicates the complexity of the test method for examination purposes. Subscript 1 indicates relatively simple test methods, subscript 2 indicates moderate test methods and subscript 3 indicates complex text methods.

[2] SRM—Standard reference materials may be obtained from the National Bureau of Standards. Ordering information may be obtained from the Office of Standard Reference Materials, B311 Chemistry Bldg., National Bureau of Standards, Washington, D.C. 20234 (telephone 301-921-2045).

[3] NBS sieve verification service—Information may be obtained from the Dimensional Metrology Section, B104 Metrology Bldg., National Bureau of Standards, Washington, D.C. 20234 (J. Beers, telephone 301-921-2216).

[4] TIM CRP—Collaborative reference program on thermal insulation materials sponsored by the Collaborative Testing Services, Inc. Information may be obtained from NBS Collaborative Reference Programs, B360 Polymer Bldg., National Bureau of Standards, Washington, D.C. 20234 (telephone 301-921-2946).

[5] Laboratory need be in only one CRP of D04, D05 and D07.

[6] TMVS—Testing machine verification service is obtainable from a number of sources. Specify verification to ASTM Standard E4. Most manufacturers of testing machines can provide information on sources of verification service.

[7] Participation in CRP for S01 and S02 is required for accreditation for S01 through S08 and S11, and in either TAPPI CRP or TIM CRP for S01 and S02 for accreditation for S10.

[8] Eligible for accreditation only if accredited for 01/S03.

[9] TAPPI CRP—Collaborative reference program sponsored by the Technical Association of the Pulp & Paper Industry. Information may be obtained from NBS Collaborative Reference Programs, B360 Polymer Bldg., National Bureau of Standards, Washington, D.C. 20234 (telephone 301-921-2946).

[10] Participation in T02 CRP required for C177 accreditation for any material. In addition, T01 or T02 participation required for accreditation for indicated materials.

[11] Not required if in T02.

[12] Not required if in T03.

[13] Not required if in T01.

[14] Eligible for accreditation only if laboratory is accredited for C177, C236 or C518 for same class of materials.

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[3510-13]

NATIONAL VOLUNTARY LABORATORY ACCREDITATION PROGRAM

Estimated Fees and Charges To Accredit Laboratories Which Test Thermal Insulation Materials

In a separate notice appearing in this issue of the FEDERAL REGISTER, the Department of Commerce announced the issuance of proposed criteria for accrediting testing laboratories which test thermal insulation materials. Pursuant to paragraph (a) of section 7.10 of the procedures for a national voluntary laboratory accreditation program (15 CFR Part 7) notice is hereby given of the estimated fees and charges which the Secretary of Commerce (Secretary) proposes to establish for this laboratory accreditation program (LAP). The proposed schedule of estimated fees and charges is furnished for informational and guidance purposes so the public may evaluate the proposed criteria in light of the expected fees to be charged.

The estimated fees and charges are in amounts calculated to cover the cost of examining, accrediting, and auditing laboratories that test thermal insulation materials. The cost associated with developing this LAP has not been included. The estimated fees and charges are intended to pay for the evaluation of information supplied by the laboratory in response to a questionnaire, for onsite inspection of the laboratory facilities, and for the participation of the laboratory in proficiency sample testing programs.

Basis for estimates. These fees and charges are based on the assumption that each laboratory that tests thermal insulation materials will be evaluated every 2 years (plus or minus 3 months), and that approximately one-third of such laboratories will undergo one unannounced reinspection during this period. The bulk of the costs will accrue during the first year of accreditation when each of the laboratories is visited and examined. However, these costs would be spread over a 2-year period so that fees would be charged annually and accreditation (or reaccreditation) would be issued annually. This accreditation procedure would insure a specific review of proficiency sample test results from each laboratory on a scheduled basis and would be a basis for identifying those laboratories which would be subject to the unannounced reinspection.

It is unlikely that any one laboratory will seek accreditation for all 53 test methods which are included in this LAP. Therefore, the fees and charges are of necessity flexible, allowing the total charges to vary with the number and complexity of the individual test methods selected by the laboratory.

Estimated fees and charges. The first element of the estimated fee is composed of a fixed charge to cover personnel costs incurred in the examination of the laboratory to meet the general criteria and basic travel cost of the inspector to the laboratory. To the fixed charge will be added a charge which varies depending upon the number and level(s) of complexity of the test method(s) selected. The fee to any laboratory will be determined by the following equation:

$$F=A+B_1(N_1)+B_2(N_2)+B_3(N_3)$$

where F is the fee in dollars, A is the fixed charge in dollars, B is the variable charge in dollars and N is the number of test methods for which the laboratory requests accreditation. Subscripts 1, 2, and 3 represent the three levels of complexity into which the test methods fall when considered for examination purposes. The fee for the simpler test methods is represented as B_1. N_1 is the number of such test methods. Test methods of intermediate complexity are represented by B_2 and N_2 in the equation, and the most complex test methods are represented by B_3 and N_3. Estimated values for each element in the equation are: A=$650, B_1=$25, B_2=$75, and B_3=$125. The level of complexity for each test method is shown by the letter B with subscript 1, 2, or 3 in the first column of appendix 1 to the FEDERAL REGISTER announcement referenced in the first sentence of this notice.

Proficiency sample fees. In addition to the basic inspection and evaluation charges referenced above, there will be a fee associated with participation in proficiency sample tests where such tests are required. The last column in appendix 1 referred to above labeled "Requisite Reference Programs" identifies those test methods for which proficiency sample tests are anticipated. Proficiency sample fees pay for distribution of samples (where appropriate), the collection and analysis of the data, and the reporting of requests. The estimated annual fee for the proficiency sample testing associated with each of the test methods is nominally $80. In arriving at this figure, it has been assumed that two proficiency samples will be provided each year.

Example calculation. In order to clearly illustrate the way the annual fee would be calculated, the following example is provided. If a laboratory was to choose to be accredited for four simple test methods (B_1), three intermediate test methods (B_2) and two complex test methods (B_3), the fee equation would become:

$$F=\$650+\$25(4)+\$75(3)+\$125(2)=\$1,225$$

Added to this would be the cost of proficiency samples. If proficiency sample tests were required for two of these nine test methods at a cost of $80 each, the total cost of proficiency sample testing would be $160. The total annual accreditation fee for the testing laboratory in this example would be $1,385.

Inquiries. Any inquiries may be addressed to Dr. Howard I. Forman, Deputy Assistant Secretary for Product Standards, Room 3876, U.S. Department of Commerce, Washington, D.C. 20230, 202-377-3221.

Dated: September 26, 1978.

JORDAN J. BARUCH,
Assistant Secretary for Science and Technology.

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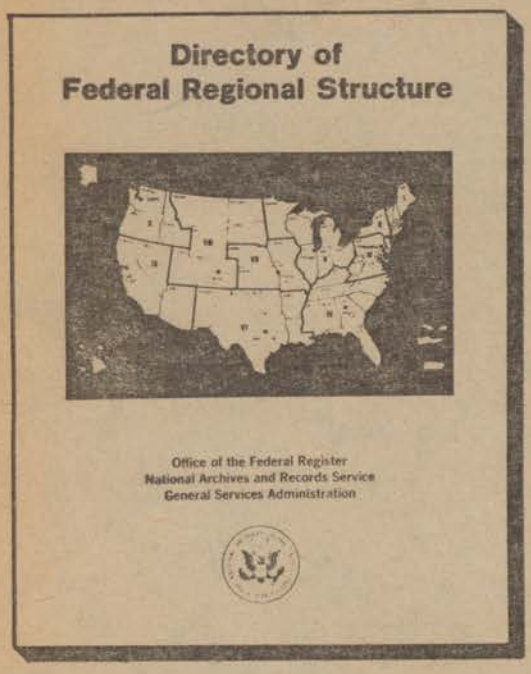

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