

FRIDAY, DECEMBER 22, 1978



highlights

"THE FEDERAL REGISTER—WHAT IT IS AND HOW TO USE IT"

For workshops in Washington, D.C., see notice on inside front cover.

GAS AND ELECTRIC UTILITIES

DOE publishes the list for 1979 identifying each gas and electric utility to which the Public Utility Regulatory Policies Act of 1978 and the National Energy Conservation Policy Act of 1978 apply 59836

BUSINESS AND INDUSTRIAL LOAN PROGRAMS

USDA/FmHA amends rules expanding eligibility criteria and expediting clearances; effective 12-22-78 59827

HAZARDOUS MATERIALS

Labor/OSHA proposes to revise rules regarding emergency exits, storage of certain gases, and fire protection equipment; comments by 3-16-79 (Part V of this issue) 60048

MICROWAVE OVENS

HEW/FDA announces guideline for petitions for exemption from warning label requirements 59906

MOBILE HOMES

HUD/FHC proposes increase in loan maturity; comments by 1-22-79 59849

TAXES

Treasury/IRS proposes guidelines relating to the application of effective date provisions of a new tax on generation-skipping transfers; comments by 2-20-79 59849

BICYCLES

CPSC revises safety standard rules (Part IV of this issue) 60034

HUD MINIMUM PROPERTY STANDARDS

HUD/FHC establishes a settling density for insulation in wall cavities; effective 1-22-79 59838

RECOMBINANT DNA RESEARCH

HEW/NIH publishes revised guidelines (2 documents) (Parts VI and VII) 60048, 60080

HEW/FDA issues notice of intent to propose regulations governing DNA work performed in connection with products subject to FDA jurisdiction; comments by 2-20-79 (Part VIII of this issue) 60134

NONCLINICAL LABORATORY STUDIES

HEW/FDA issues rules pertaining to good laboratory practices; effective 6-20-79 (Part II of this issue) 59986

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HOW TO USE THE FEDERAL REGISTER WORKSHOPS

Washington, D.C. Workshops

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

WHAT: Free Friday workshops presenting:

1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between Federal Register and the Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

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.

WHEN: January 12, 26; February 9, 23; or March 9, 23—from 9–11:30 a.m.

WHERE: Office of the Federal Register, Room 9409, 1100 L Street NW., Washington, D.C.

RESERVATIONS: Call Mike Smith, Workshop Coordinator, 202-523-5235.

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Phone 523-5240

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NOTE: A complete listing of all public laws from the second session of the 95th Congress was published as Part II of the issue of December 4, 1978. (Price: 75 cents. Order by stock number 022-003-00960-4 from the Superintendent of Documents, Government Printing Office, Washington, D.C. 20402, Telephone 202-275-3030.)

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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.

[6325-01-M]

Title 5—Administrative Personnel

CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Cabinet Committee on Opportunities for Spanish-Speaking People, National Aeronautics and Space Council, and National Study Commission on Records and Documents of Federal Officials

AGENCY: Civil Service Commission.

ACTION: Final Rule.

SUMMARY: This amendment revokes the Schedule A authorities for the Cabinet Committee on Opportunities for Spanish-Speaking People, the National Aeronautics and Space Council, and the National Study Commission on Records and Documents of Federal Officials because these organizations no longer exist.

EFFECTIVE DATE: December 5, 1978.

FOR MORE INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3123, 5 CFR 213.3162, and 5 CFR 213.3199(t) are revoked, as follows:

§ 213.3123 [Revoked]

* * *

§ 213.3162 [Revoked]

* * *

§ 213.3199 Temporary boards and commissions.

* * *

(t) [Revoked]

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION,
JAMES C. SPRY,

*Executive Assistant
to the Commissioners.*

[FR Doc. 78-35283 Filed 12-21-78; 8:45 am]

[6325-01-M]

PART 213—EXCEPTED SERVICE

National Foundation on the Arts and the Humanities

AGENCY: Civil Service Commission.

ACTION: Final rule.

SUMMARY: This amendment excepts under Schedule B until September 30, 1980, one position of Assistant Director in the Public Libraries Program, Division of Public Programs, National Endowment for the Humanities because competitive examination for this position is impracticable.

EFFECTIVE DATE: December 4, 1978.

FOR FURTHER INFORMATION CONTACT:

William Bohling, 202-632-4533.

Accordingly, 5 CFR 213.3282(b)(26) is added as follows:

§ 213.3282 National Foundation on the Arts and the Humanities.

* * *

(b) *National Endowment for the Humanities.* * * *

(26) Until September 30, 1980, one position of Assistant Director, Public Libraries Program, Division of Public Programs.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954-1958 Comp., p. 218.)

UNITED STATES CIVIL SERVICE COMMISSION.

JAMES C. SPRY,
*Executive Assistant
to the Commissioners.*

[FR Doc 78-35450 Filed 12-21-78; 8:45 am]

[3410-30-M]

Title 7—Agriculture

CHAPTER II—FOOD AND NUTRITION SERVICE, DEPARTMENT OF AGRICULTURE

AUDITS OF CERTAIN FNS PROGRAMS

Interim Regulations

AGENCY: Food and Nutrition Service, USDA.

ACTION: Interim regulations.

SUMMARY: These interim regulations modify the regulatory audit coverage prescribed for the National School Lunch Program, the Special Milk Program for Children, the School Breakfast Program and the Food Service Equipment Assistance Program. Current regulations require that each of these programs be audited at both State and local levels not less frequently than once every two years. This requirement exceeds the audit coverage mandated for Federal grant programs by Office of Management and Budget Circulars A-102, Uniform Administrative Requirements For Grants-In-Aid To State and Local Governments, and A-110, Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Nonprofit Organizations. The interim regulations presented in this document are necessary to bring the regulations governing the programs named above into prompt compliance with the Circulars.

DATES: These regulations must take effect no later than July 1, 1979. Comments must be received on or before March 30, 1979 to be assured of consideration.

ADDRESS: Send comments to Margaret O'K Glavin, Acting Director, School Programs Division, Food and Nutrition Service, USDA, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT:

Margaret O'K Glavin, Acting Director, School Programs Division, Food and Nutrition Service, USDA, Washington, D.C. 20250 (202-447-8130).

SUPPLEMENTARY INFORMATION: The four amendments contained in

this document affect the audit coverage required for the National School Lunch Program (Part 210), the Special Milk Program for Children (Part 215), the School Breakfast Program (Part 220) and the Food Service Equipment Assistance Program (Part 230). All four programs are subject to the same audit requirement. Each respective Part is hereby amended to implement this requirement.

The regulatory amendments presented in this document affect the audit coverage required for the school nutrition programs (National School Lunch Program, Special Milk Program for Children, School Breakfast Program, and Food Service Equipment Assistance Program). The regulations governing these programs were expanded in 1975-76 to include the applicable provisions of Federal Management Circular 74-7. This Circular prescribed uniform administrative requirements for Federal grant programs, including a requirement that grantee financial management systems provide for biennial audits. Under the school nutrition programs, the grantees are the State agencies, and certain private School Food Authorities for whom the Food and Nutrition Service administers the programs directly. State administered School Food Authorities, both public and private, are subgrantees of the State agency. Pursuant to the Circular provision, the Food and Nutrition Service added to each applicable Part of the regulations the requirement that each respective program be audited at the State agency and School Food Authority level not less frequently than once every two years. Such audits were to be comprehensive, entailing coverage of each program's "funds and operations."

Since the promulgation of these amendments, there have been many objections to the imposed audit requirement. Many Federal, State and local officials have contended that USDA is requiring excessive audit coverage. Such coverage may be appropriate for State agencies, and for large city school districts that account for over eighty percent of USDA's program disbursements. However, it would impose a severe burden upon the many small School Food Authorities participating in the school nutrition programs, and biennial audit coverage of many such entities would not be cost-effective. Thus, a need was identified for a mechanism providing relief to small School Food Authorities without compromising the Government's interest.

On September 12, 1977, the Office of Management and Budget issued OMB Circular A-102. This document superceded Federal Management Circular 74-7 and clarified several of the issu-

ing Agency's intentions that had been ambiguously expressed in the latter. One such ambiguous area concerned required audit coverage. Attachment G to OMB Circular A-102 clarified the Office of Management and Budget's intention that every grantee and subgrantee organization, rather than every Federal grant program operated by such organization, must be audited biennially. The Office of Management and Budget envisioned that each audit would include a random sample of the Federal grant programs operated by each auditee, and cover the auditee's (1) financial management and (2) compliance with the terms and conditions of the Federal grants (i.e., those aspects of the regulations that affect the auditee's entitlement to Federal funds.) Consequently, the audit requirement set forth in our current regulations exceeds the intent of the Circular with respect to both audit frequency and audit scope. The amendments presented in this document would restrict the minimum audit coverage required for the school nutrition programs to that envisioned by the Office of Management and Budget, as well as provide relief from this requirement to certain small School Food Authorities. Due to the urgent need to achieve prompt compliance with the Circulars, it was considered necessary to issue these amendments as interim regulations rather than as proposed rules, it being found impracticable and contrary to the public interest to issue them as proposed rules.

All persons who desire to comment on these interim regulations are encouraged to do so. Comments are especially invited from State agency and School Food Authority personnel directly involved in administering and auditing the school nutrition programs. All written submissions received pursuant to this notice will be made available for public inspection at the School Programs Division, Food and Nutrition Service, during regular business hours (8:30 a.m. to 5:00 p.m.) (7 CFR 1.27(b)).

7 CFR Chapter II is amended as follows:

PART 210—NATIONAL SCHOOL LUNCH PROGRAM

1. In § 210.17, paragraph (a) is revised to read as follows:

§ 210.17 Management evaluations and audits.

(a)(1) In accordance with the plan submitted under § 210.4a(b)(6), the State agency shall ensure that all organizations within the State that administer or participate in the Program covered by this Part obtain audits as required by Office of Management and Budget Circulars A-102 or A-110, as applicable. The term "organization",

as used in this section, shall refer to the entity whose financial management system controls the receipt, custody and disbursement of the Federal grant funds made available for the Program. The audits shall ascertain the effectiveness of the financial management systems and internal procedures that have been established by the auditee organization to meet the terms and conditions of its Federal grants. It is not required that the Program covered by this Part be included in every audit. Rather, the audits shall be conducted on an organization-wide basis, and shall include an appropriate random sampling of Federal grant programs administered or operated by the auditee organization. The Program covered by this part shall be adequately represented in the universe from which each such sample is selected.

(2) The State agency, or FNSRO where applicable, shall establish procedures to ensure that it obtains the following information pertaining to each School Food Authority organization under its jurisdiction: (i) the names of the Federal grant programs included in each audit obtained by the School Food Authority pursuant to the requirements of this Part, regardless of whether such programs include the Program covered by this Part; and (ii) the nature of any deficiencies intrinsic to the auditee's grants management system as revealed by audit. When system deficiencies, as discussed in the preceding sentence, are reported in audits that did not specifically test the program covered by this Part, the State agency, or FNSRO where applicable, should make, or cause to be made, follow-up audits to determine the impact of such deficiencies upon the program covered by this Part. The State agency, or FNSRO where applicable, shall establish procedures to assure timely and appropriate resolution of audit findings and recommendations, including findings relating to deficiencies such as those cited in paragraph (a)(2)(ii), above, which may impact upon the Program covered by this Part.

(3) Audits shall be made in accordance with generally accepted auditing standards, including the standards published by the General Accounting Office, Standards for Audit of Governmental Organizations, Programs, Activities and Functions. Audits may be made by any of the following audit groups: (i) School Food Authority and State agency staff auditors who are totally independent of the auditee; (ii) State Auditors General; (iii) State Comptrollers; (iv) other comparable independent State audit groups; (v) Certified Public Accountants or (vi) State licensed public accountants.

(4) Except as provided for in this section, each organization at the State

agency and School Food Authority level shall obtain audits, meeting the conditions discussed in this section, on a continuing basis or at scheduled intervals, usually annually, but not less frequently than once every two years. The State agency, or FNSRO where applicable, may elect not to require this audit frequency of School Food Authority organizations to which *Both* of the following conditions apply: (i) the only Federal grant program or programs operated by the School Food Authority organization are the Program covered by this part, the Special Milk Program for Children, the School Breakfast Program, the Food Service Equipment Assistance Program, or any combination of such programs; and (ii) the level of Federal grant funds disbursed to the School Food Authority organization in any fiscal year does not exceed \$10,000; *provided, however*, that the State agency, or FNSRO where applicable, shall make or require an audit of such a School Food Authority when conditions indicate a need for such an audit.

(Catalogue of Federal Domestic Assistance No. 10.555)

PART 215—SPECIAL MILK PROGRAM FOR CHILDREN

2. In § 215.13, paragraph (a) is revised to read as follows:

§ 215.13 Management evaluations and audits.

(a)(1) In accordance with the plan submitted under § 210.4a, § 225.8 or § 226.7 of this chapter, the State agency shall ensure that all organizations within the State that administer or participate in the Program covered by this part obtain audits as required by Office of Management and Budget Circulars A-102 or A-110, as applicable. The term "organization", as used in this section, shall refer to the entity whose financial management system controls the receipt, custody and disbursement of the Federal grant funds made available for the Program. The audits shall ascertain the effectiveness of the financial management systems and internal procedures that have been established by the auditee organization to meet the terms and conditions of its Federal grants. It is not required that the Program covered by this part be included in every audit. Rather, the audits shall be conducted on an organization-wide basis, and shall include an appropriate random sampling of Federal grant programs administered or operated by the auditee organization. The Program covered by this part shall be adequately represented in the universe from which each such sample is selected.

(2) The State agency, or FNSRO where applicable, shall establish procedures to ensure that it obtains the following information pertaining to each School Food Authority or child-care institution organization under its jurisdiction: (i) the names of the Federal grant programs included in each audit obtained by the School Food Authority or child-care institution pursuant to the requirements of this part, regardless of whether such programs include the Program covered by this part; and (ii) the nature of any deficiencies intrinsic to the auditee's grants management system as revealed by audit. When system deficiencies, as discussed in the preceding sentence, are reported in audits that did not specifically test the Program covered by this Part, the State agency, or FNSRO where applicable, should make, or cause to be made, follow-up audits to determine the impact of such deficiencies upon the Program covered by this part. The State agency, or FNSRO where applicable, shall establish procedures to assure timely and appropriate resolution of audit findings and recommendations, including findings relating to deficiencies such as those cited in paragraph (a)(2)(ii), above, which may impact upon the Program covered by this part.

(3) Audits shall be made in accordance with generally accepted auditing standards, including the standards published by the General Accounting Office, Standards for Audit of Governmental Organizations, Programs, Activities and Functions. Audits may be made by any of the following audit groups: (i) School Food Authority and State agency staff auditors who are totally independent of the auditee; (ii) State Auditors General; (iii) State Comptrollers; (iv) other comparable independent State audit groups; (v) Certified Public Accountants or (vi) State licensed public accountants.

(4) Except as provided for in this section, each organization at the State agency, School Food Authority and child-care institution level shall obtain audits, meeting the conditions discussed in this section, on a continuing basis or at scheduled intervals, usually annually, but not less frequently than once every 2 years. The State agency, or FNSRO where applicable, may elect not to require this audit frequency of School Food Authority organizations to which *both* of the following conditions apply: (i) The only Federal grant program or programs operated by the School Food Authority organization are the Program covered by this part, the National School Lunch Program, the School Breakfast Program, the Food Service Equipment Assistance Program, or any combination of such

programs; and (ii) the level of Federal grant funds disbursed to the School Food Authority organization in any fiscal year does not exceed \$10,000; *provided, however*, that the State agency, or FNSRO where applicable, shall make or require an audit of such a School Food Authority when conditions indicate a need for such an audit. The provision of the preceding sentence does not apply to child-care institutions as defined in § 215.2(c) of this part.

(Catalogue of Federal Domestic Assistance No. 10.556.)

PART 220—SCHOOL BREAKFAST PROGRAM

3. In § 220.15, paragraph (a) is revised to read as follows:

§ 220.15 Management evaluations and audits.

(a)(1) In accordance with the plan submitted under § 210.4a(b)(6), the State agency shall ensure that all organizations within the State that administer or participate in the Program covered by this Part obtain audits as required by Office of Management and Budget Circulars A-102 or A-110, as applicable. The term "organization", as used in this section, shall refer to the entity whose financial management system controls the receipt, custody and disbursement of the Federal grant funds made available for the Program. The audits shall ascertain the effectiveness of the financial management systems and internal procedures that have been established by the auditee organization to meet the terms and conditions of its Federal grants. It is not required that the Program covered by this Part be included in every audit. Rather, the audits shall be conducted on an organization-wide basis, and shall include an appropriate random sampling of Federal grant programs administered or operated by the auditee organization. The Program covered by this Part shall be adequately represented in the universe from which each such sample is selected.

(2) The State agency, or FNSRO where applicable, shall establish procedures to insure that it obtains the following information pertaining to each School Food Authority organization under its jurisdiction: (i) The names of the Federal grant programs included in each audit obtained by the School Food Authority pursuant to the requirements of this Part, regardless of whether such programs include the Program covered by this Part; and (ii) the nature of any deficiencies intrinsic to the auditee's grants management system as revealed by audit.

When system deficiencies, as discussed in the preceding sentence, are reported in audits that did not specifically test the Program covered by this Part, the State agency, or FNSRO where applicable, should make, or cause to be made, follow-up audits to determine the impact of such deficiencies upon the Program covered by this Part. The State agency, or FNSRO where applicable, shall establish procedures to assure timely and appropriate resolution of audit findings and recommendations including findings relating to deficiencies such as those cited in paragraph (a)(2)(ii) above, which may impact upon the Program covered by this Part.

(3) Audits shall be made in accordance with generally accepted auditing standards, including the standards published by the General Accounting Office, Standards for Audit of Governmental Organizations, Programs, Activities and Functions. Audits may be made by any of the following audit groups: (i) School Food Authority and State agency staff auditors who are totally independent of the auditee; (ii) State Auditors General; (iii) State Comptrollers; (iv) other comparable independent State audit groups; (v) Certified Public Accountants or (vi) State licensed public accountants.

(4) Except as provided for in this section, each organization at the State agency and School Food Authority level shall obtain audits, meeting the conditions discussed in this section, on a continuing basis or at scheduled intervals, usually annually, but not less frequently than once every 2 years. The State agency, or FNSRO where applicable, may elect not to require this audit frequency of School Food Authority organizations to which both of the following conditions apply: (i) The only Federal grant program or programs operated by the School Food Authority organization are the Program covered by this Part, the National School Lunch Program, the Special Milk Program for Children, the Food Service Equipment Assistance Program, or any combination of such programs; and (ii) the level of Federal grant funds disbursed to the School Food Authority organization in any fiscal year does not exceed \$10,000; *provided, however*, that the State agency, or FNSRO where applicable, shall make or require an audit of such a School Food Authority when conditions indicate a need for such an audit.

(Catalogue of Federal Domestic Assistance No. 10.553)

PART 230—NONFOOD ASSISTANCE PROGRAM

4. In § 230.14, paragraph (a) is revised to read as follows:

§ 230.14 Management evaluations and audits.

(a)(1) Each State agency shall ensure that all organizations within the State that administer or participate in the Program covered by this part obtain audits as required by Office of Management and Budget Circulars A-102 or A-110, as applicable. The term "organization", as used in this section, shall refer to the entity whose financial management system controls the receipt, custody and disbursement of the Federal grant funds made available for the Program. The audits shall ascertain the effectiveness of the financial management systems and internal procedures that have been established by the auditee organization to meet the terms and conditions of its Federal grants. It is not required that the Program covered by this part be included in every audit. Rather, the audits shall be conducted on an organization-wide basis, and shall include an appropriate random sampling of Federal grant programs administered or operated by the auditee organization. The Program covered by this part shall be adequately represented in the universe from which each such sample is selected.

(2) The State agency, or FNSRO where applicable, shall establish procedures to ensure that it obtains the following information pertaining to each School Food Authority organization under its jurisdiction: (i) The names of the Federal grant programs included in each audit obtained by the School Food Authority pursuant to the requirements of this part, regardless of whether such Programs include the Program covered by this part; and (ii) the nature of any deficiencies intrinsic to the auditee's grants management system as revealed by audit. When system deficiencies, as discussed in the preceding sentence, are reported in audits that did not specifically test the Program covered by this part, the State agency, or FNSRO where applicable, should make, or cause to be made, follow-up audits to determine the impact of such deficiencies upon the Program covered by this part. The State agency, or FNSRO where applicable, shall establish procedures to assure timely and appropriate resolution of audit findings and recommendations, including findings relating to deficiencies such as those cited in paragraph (a)(2)(ii), above, which may impact upon the Program covered by this part.

(3) Audits shall be made in accordance with generally accepted auditing standards, including the standards published by the General Accounting Office, Standards for Audit of Governmental Organizations, Programs, Activities and Functions. Audits may be made by any of the following audit groups: (i) School Food authority and State agency staff auditors who are totally independent of the auditee; (ii) State Auditors General; (iii) State Comptrollers; (iv) other comparable independent State audit groups; (v) Certified Public Accountants or (vi) State licensed public accountants.

(4) Except as provided for in this section, each organization at the State agency and School Food Authority level shall obtain audits, meeting the conditions discussed in this section, on a continuing basis or at scheduled intervals, usually annually, but not less frequently than one every two years. The State agency, or FNSRO where applicable, may elect not to require this audit frequency of School Food Authority organizations to which both of the following conditions apply: (i) The only Federal grant program or programs operated by the School Food Authority organization are the Program covered by this part, the National School Lunch Program, the Special Milk Program for Children, the School Breakfast Program, or any combination of such programs; and (ii) the level of Federal grant funds disbursed to the School Food Authority organization in any fiscal year does not exceed \$10,000; *provided, however*, that the State agency, or FNSRO where applicable, shall make or require an audit of such a School Food Authority when conditions indicate a need for such an audit.

(Catalogue of Federal domestic Assistance No. 10.554)

NOTE.—The Food and Nutrition Service has determined that this document does not contain a major proposal requiring preparation of an Economic Impact statement under Executive Order 11821 and OMB Circular A-107.

(Pub. L. 89-642, 80 Stat. 885-890, as amended by the Child Nutrition Act of 1966)

Dated: December 19, 1978.

CAROL TUCKER FOREMAN,
Assistant Secretary.

[FR Doc. 78-35841 Filed 12-21-78; 8:45 am]

[3810-02-M]

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

[Lemon Reg. 178; Lemon Reg. 177, Amdt. 11]

PART 910—LEMONS GROWN IN CALIFORNIA AND ARIZONA

Limitation of Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This action establishes the quantity of California-Arizona lemons that may be shipped to the fresh market during the period December 24-30, 1978, and increases the quantity of such lemons that may be so shipped during the period December 17-23. Such action is needed to provide for orderly marketing of fresh lemons for the periods specified due to the marketing situation confronting the lemon industry.

DATES: The regulation becomes effective December 24, 1978, and the amendment is effective for the period December 17-23, 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, established under this marketing order, 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. This regulation has not been determined significant under the USDA criteria for implementing Executive Order 12044.

The committee met on December 19, 1978, to consider supply and market conditions and other factors affecting the need for regulation, and recommended quantities of lemons deemed advisable to be handled during the specified weeks. The committee reports the demand for lemons is easier.

It is further found that it is impracticable and contrary to the public in-

terest to give preliminary notice, engage in public rulemaking, and postpone the effective date until 30 days after publication in the FEDERAL REGISTER (5 U.S.C. 553), because of insufficient time between the date when information became available upon which this regulation and amendment are 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, and the amendment relieves restrictions on the handling of lemons. 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.

§ 910.478 Lemon Regulation 178.

Order. (a) The quantity of lemons grown in California and Arizona which may be handled during the period December 24, 1978, through December 30, 1978, is established at 190,000 cartons.

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

§ 910.477 (Amended).

2. Paragraph (a) of § 910.477 Lemon Regulation 177 (43 FR 58542) is amended to read as follows: "The quantity of lemons grown in California and Arizona which may be handled during the period December 17, 1978, through December 23, 1978, is established at 250,000 cartons."

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

Dated: December 21, 1978.

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

[FR Doc 78-35921 Filed 12-21-78; 11:12 am]

[3410-05-M]

CHAPTER XIV—COMMODITY CREDIT CORPORATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS, PURCHASES AND OTHER OPERATIONS

PART 1425—COOPERATIVE MARKETING ASSOCIATIONS

Subpart—Eligibility Requirements for Price Support

MISCELLANEOUS AMENDMENTS, CORRECTION

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final Rule.

SUMMARY: An amendment specifying 15 days as the period of time in which an approved cooperative, participating in a price support program, must distribute to its members proceeds received through CCC price support loans and purchases was issued on February 3, 1978, and published in the FEDERAL REGISTER (43 FR 4589). The authority citation for this action was inadvertently omitted. This document is being published to show the proper authority citation.

EFFECTIVE DATE: The final rule became effective on February 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Charlie B. Robbins (ASCS), 202-447-4634, P.O. Box 2415, Washington, D.C. 20013.

FINAL RULE

The amendment to 7 CFR Part 1425 (43 FR 4589) is amended to add at the end thereof the citation for the amendment as follows:

(Secs. 4 and 5, 62 Stat. 1070, as amended (15 U.S.C. 714b and c); Secs. 101, 103, 203, 301, 401, 63 Stat. 1051, as amended (7 U.S.C. 1444(a), 1441, 1446d, 1447, 1421(a)).)

Signed at Washington, D.C., on December 15, 1978.

RAY FITZGERALD,
Executive Vice President,
Commodity Credit Corporation.

[FR Doc. 78-35575 Filed 12-21-78; 8:45 am]

[3410-07-M]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER P—GUARANTEED LOANS

PART 1980—GENERAL

Subpart E—Business and Industrial Loan Programs

ELIGIBILITY CRITERIA AND LOAN PURPOSES AND PROCESSING OF CLEARANCES

AGENCY: Farmers Home Administration, USDA.

ACTION: Final rule.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations pertaining to the Business and Industrial loan program. The intended effect of this action is to expand the eligibility criteria and loan purposes and expedite the processing of clearances required in the program. This action results from recent legislation and internal administrative processing changes.

EFFECTIVE DATE: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Darryl H. Evans, Loan Specialist, telephone 202-447-4150.

SUPPLEMENTARY INFORMATION: Various sections of Subpart E of Part 1980, Chapter XVIII, Title 7, Code of Federal Regulations are amended. Section 1980.402(a) which sets forth the definitions for the program is expanded by amending paragraphs (f) and (g) dealing with the definition of State. The change adds Guam, American Samoa, and the Northern Mariana Islands. This amendment is made in accordance with provisions of the Agricultural Credit Act of 1978, Pub. L. 95-334, which was effective August 4, 1978.

Section 1980.411(a) is amended to add an additional subparagraph (16) which includes aquaculture as an eligible loan purpose. This change is made in accordance with provisions of the Agricultural Credit Act of 1977, Pub. L. 95-113, which was effective September 29, 1977.

Section 1980.451, paragraphs B3(c) and "Note" under the heading "Administrative" is revised to exempt loans of \$1 million and under from the character evaluation administrative process. This action was necessitated by the fact that the Inspector General of U.S. Department of Agriculture could no longer process all the thousands of Forms FmHA 449-4, "Statement of Personal History," since such procedures were not cost effective. The State Director may process Form FmHA 449-4 for any project, regardless of size, that he or she believes is in the best interest of the Government. Form FmHA 449-4 will still be required of the applicant on loans of \$1 million or less as part of the overall application package. The lender is responsible for assuring that Form FmHA 449-4 is completed accurately. This change will reduce the processing workload considerably and is consistent with other recent amendments on processing and approving loan applications. It will also reduce overall loan processing time on smaller applications. Since this change is procedural in nature and the above changes are

mandated by recent legislation, publication in prior rule making format is unnecessary.

Accordingly, Subpart E of Part 1980 is amended as follows:

§ 1980.402 [Amended]

1. Section 1980.402(f) is amended by deleting the first "comma" after the word "State" and the words "the Commonwealth of Puerto Rico, or the Virgin Islands" from the first sentence.

2. Section 1980.402(g) is revised to read as follows:

§ 1980.402 Definitions.

(g) *State*. Any of the fifty states, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

3. Section 1980.411(a) is amended by adding a new subparagraph (16) which reads as follows:

§ 1980.411 Loan purposes.

(a) *Private entrepreneurs*. * * *

(16) Aquaculture including conservation, development, and utilization of water for aquaculture purposes. Aquaculture means the culture or husbandry of aquatic animals or plants by private industry for the purpose of creating or augmenting publicly-owned and regulated stocks of fish.

4. In § 1980.451, paragraph B3(c) and "Note" under "Administrative" is revised to read as follows:

§ 1980.451 Filing and processing applications.

ADMINISTRATIVE

B. The State Director:

3. * * *

(c) Form FmHA 449-4 (5 copies) for all loans over \$1,000,000 or for loans, regardless of size, where the State Director believes a character evaluation is advisable. Applicants should be advised that these clearances will take approximately 60 days to process and that the National Office will take no action to expedite such processing.

NOTE.—Forms FmHA 449-2 and 449-4 should only be processed if a complete preapplication or application has been received.

(7 U.S.C. 1989; delegation of authority by the Secretary of Agriculture, 7 CFR 2.23; delegation of authority by the Assistant Secretary of Agriculture for Rural Development, (7 CFR 2.70.)

NOTE.—This document has been reviewed in accordance with FmHA Instruction 1901-G, "Environmental Impact Statement." It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969, Pub. L. 91-190, an Environmental Impact Statement is not required.

This regulation has not been determined significant under the USDA criteria implementing Executive Order 12044.

Dated: December 11, 1978.

A. JENNINGS ORR,
Acting Administrator,
Farmers Home Administration.

[FR Doc. 78-35576 Filed 12-21-78; 8:45 am]

[3410-37-M]

CHAPTER XXVIII—FOOD SAFETY AND QUALITY SERVICE (FRUIT AND VEGETABLE QUALITY DIVISION), DEPARTMENT OF AGRICULTURE

SUBCHAPTER E—EXPORT AND DOMESTIC CONSUMPTION PROGRAMS

PART 2880—FRESH IRISH POTATOES

Subpart—Fresh Irish Potatoes—Livestock Feed Diversion Program

CORRECTION

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule—correction.

SUMMARY: This document corrects the chapter number appearing twice in FR Doc. 78-33055 regarding the Livestock Feed Diversion Program.

EFFECTIVE DATE: November 20, 1978.

FOR FURTHER INFORMATION CONTACT:

D. A. Thibeault, Chief, Commodity Procurement Branch, Fruit and Vegetable Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-2781.

FINAL RULE—CORRECTION

In FR Doc. 78-33055 appearing at page 54921 in the FEDERAL REGISTER of

Friday, November 24, 1978, the following corrections are made:

1. In the document heading, reference to "Chapter I" is corrected to read "Chapter XXVIII."

2. The amendatory language to Part 2880 is corrected to read as follows:

"Accordingly, 7 CFR, Chapter XXVIII, is amended by adding a new Subchapter E, Part 2880 to read as follows:"

Done at Washington, D.C., on December 19, 1978.

D. L. HOUSTON,
Acting Administrator,
Food Safety and Quality Service.

[FR Doc. 78-35663 Filed 12-21-78; 8:45 am]

[6320-01-M]

Title 14—Aeronautics and Space

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER A—ECONOMIC REGULATIONS

[Reg. ER-1085; Amdt. of CH II]

ORGANIZATIONAL CHANGE

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., December 14, 1978.

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This rule reflects the consolidation of the Bureau of Fares and Rates and the Bureau of Operating Rights into a new Bureau of Pricing and Domestic Aviation.

DATES: Effective: December 14, 1978. Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of General Counsel, Rules Division, Civil Aeronautics Board, 1825 Connecticut Avenue, Washington, D.C. 202-673-5442.

SUPPLEMENTARY INFORMATION: For the reasons discussed in OR-140, we have consolidated the Bureau of Fares and Rates and the Bureau of Operating Rights into a new Bureau of Pricing and Domestic Aviation. The consolidation is reflected in specific amendments to Parts 312, 384, 385, and 387, which are made in PR-185 and OR-140 through OR-142, respectively. Those amendments are also being issued today.

This rule substitutes the new bureau's name for the two old names in all other Board regulations. Since this rule is administrative in nature, affecting rules of agency organization and procedure, we find that notice and public procedure are unnecessary and

that the rule may be effective immediately.

Accordingly, the Civil Aeronautics Board amends all its regulations (14 CFR Chapter II), except Parts 312, 384, 385, and 387, as follows:

"Bureau of Fares and Rates" and "Bureau of Operating Rights" are replaced by "Bureau of Pricing and Domestic Aviation" wherever they appear.

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743 (49 U.S.C. 1324); Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989 (49 U.S.C. 1324 (note)).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc 78-35684 Filed 12-21-78; 8:45 am]

[6320-01-M]

[ER-1087; Economic Regulations Amendment No. 24 to Part 214]

PART 214—TERMS, CONDITIONS, AND LIMITATIONS OF FOREIGN AIR CARRIER PERMITS AUTHORIZING CHARTER TRANSPORTATION ONLY

Editorial Amendment

AGENCY: Civil Aeronautics Board.

ACTION: Editorial amendment.

SUMMARY: The Board is correcting a drafting error in 14 CFR 214.7(b)(8). The last sentence of the proviso should refer to subparagraph (4) rather than to subparagraph (3). This editorial amendment is issued by the undersigned pursuant to the delegation of authority from the Board to the General Counsel in 14 CFR 385.19. Procedures for review of this amendment are set forth in Subpart C of Part 385 (14 CFR 385.50 through 385.54).

DATES: Effective: January 8, 1979; Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Richard B. Dyson, Civil Aeronautics Board, Office of the General Counsel, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428, 202-673-5442.

AMENDMENT

The Board hereby amends the last sentence of the Proviso of 14 CFR 214.7(b)(8) to read as follows:

Provided, . . .

With respect to subparagraphs (1), (2), and (4), of paragraph (b), each person engaging less than the entire capacity of an aircraft shall contract and pay for 40 seats, except that, if the entire capacity of an aircraft

having less than 80 seats is engaged by no more than two persons described in paragraph (b), then either one of such persons may contract and pay for a minimum of 20 seats.

(Section 204 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743; 49 U.S.C. 1324.)

By the Civil Aeronautics Board:

PHILIP J. BAKES, Jr.,
General Counsel.

[FR Doc. 78-35823 Filed 12-21-78; 8:45 am]

[6320-01-M]

[ER-1086; Economic Regulation Amendment No. 13 to Part 250]

PART 250—OVERSALES

Editorial Amendment

AGENCY: Civil Aeronautics Board.

ACTION: Editorial amendment.

SUMMARY: This rule clarifies the applicability of the Board's regulations for overbooking to make it clear that they apply to carriers certificated under the dormant authority and automatic entry provisions of the Act.

DATES: Effective: January 8, 1979. Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Joseph A. Brooks, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue NW., Washington, D.C. 20428; 202-673-5442.

SUPPLEMENTARY INFORMATION: The Airline Deregulation Act of 1978 (Pub. L. 95-504) amended section 401 of the Act by providing for certification applications to provide air transportation where the present certificated carrier has not provided minimum service and the route authority is thereby dormant. The newly certificated carrier must then provide the minimum scheduled service. It also provides for certification under the automatic entry program.

Since these dormant authority and automatic entry carriers will be providing essentially the same service under sections 401(d)(5) and 401(d)(7) of the Act, respectively, as those certificated under sections 401(d)(1) or 401(d)(2) of the Act, the Board's overbooking regulations under Part 250 of the Economic Regulations (14 CFR Part 250) should apply to them.

In order to conform these regulations to the deregulation amendments, the definition of a carrier under Part 250 is amended to include those carriers certificated under sections 401(d)(5) and 401(d)(7) of the Act.

This amendment, which is editorial and conforming in nature, is issued

pursuant to the delegation of authority from the Board to the General Counsel in § 385.19 of the Organization Regulations. Procedures for review of this amendment are set forth in Subpart C of Part 385 (14 CFR §§ 385.50 through 385.54).

Accordingly, the Board amends the definition of "carrier" in § 250.1 of its Economic Regulations (14 CFR § 250.1) to read as follows:

§ 250.1 Definitions.

"Carrier" means (a) an air carrier, except a helicopter operator, holding a certificate issued by the Board pursuant to sections 401(d)(1), 401(d)(2), 401(d)(5), or 401(d)(7) of the Act, authorizing the transportation of persons, or (b) a foreign route air carrier holding a permit issued by the Board pursuant to section 402 of the Act authorizing the transportation of persons.

(Sections 204(a) and 401 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 754 (as amended); 49 U.S.C. 1324, 1371. Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989; 49 U.S.C. 1324 (note). Pub. L. 95-504.)

By the Civil Aeronautics Board.

PHILIP J. BAKES, Jr.,
General Counsel.

[FR Doc. 78-35697 Filed 12-21-78; 8:45 am]

[6320-01-M]

SUBCHAPTER B—PROCEDURAL REGULATIONS

[Reg. PR-185; Amdt. No. 3]

PART 312—IMPLEMENTATION OF THE NATIONAL ENVIRONMENTAL POLICY ACT, INCLUDING THE PREPARATION OF ENVIRONMENTAL IMPACT STATEMENTS

Bureau of Pricing and Domestic Aviation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., December 14, 1978.

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This rule amends Part 312 of the Board's Procedural Regulations to reflect the consolidation of the Bureau of Fares and Rates and the Bureau of Operating Rights in a new Bureau of Pricing and Domestic Aviation.

DATES: Effective: December 14, 1978.
Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of General Counsel, Rules Division, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C., 202-673-5442.

SUPPLEMENTARY INFORMATION: Further information about the consolidation of the two bureaus can be found in OR-140, which is also being adopted today. Since this amendment is administrative in nature, affecting rules of agency organization and procedure, the Board finds that notice and public procedure are unnecessary and that the rule may become effective immediately.

Accordingly, the Civil Aeronautics Board amends Part 312 of its Procedural Regulations (14 CFR Part 312) as follows:

In § 312.8, paragraph (a) is amended in part to read:

§ 312.8 Designation of responsible officials.

(a) The Director of the Bureau of Pricing and Domestic Aviation and the Director of the Bureau of International Aviation, or their designees, are assigned * * *

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743, (49 U.S.C. 1324); Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989, (49 U.S.C. 1324 (note)).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35683 Filed 12-21-78; 8:45 am]

[6320-01-M]

SUBCHAPTER E—ORGANIZATIONAL REGULATION

[Reg. OR-140; Amdt. No. 13]

PART 384—STATEMENT OF ORGANIZATION, DELEGATION OR AUTHORITY, AND AVAILABILITY OF RECORDS AND INFORMATION

Creation of Bureau of Pricing and Domestic Aviation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., December 14, 1978.

AGENCY: Civil Aeronautics Board.

ACTION: Final Rule.

SUMMARY: This rule amends the Board's general statement of organization to reflect the consolidation of the Bureau of Operating Rights and the Bureau of Fares and Rates into the Bureau of Pricing and Domestic Aviation.

Specific delegations of authority are amended in OR-141, which is being issued simultaneously with this rule.

DATES: Effective: December 14, 1978.
Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of General Counsel, Rules Division, Civil Aeronautics Board, 1825 Connecticut Ave., NW., Washington, D.C., 202-673-5442.

SUPPLEMENTARY INFORMATION: This amendment reflects the consolidation of the Bureau of Operating Rights (BOR) and the Bureau of Fares and Rates (BFR) into the Bureau of Pricing and Domestic Aviation (BPDA). The new bureau performs all the functions of the two former bureaus. BPDA's functions therefore include, among others:

1. Awarding of domestic route authority;
2. Formulating all pricing policy (domestic and international);
3. Processing and performing required staff work for all fare, rate and tariff work;
4. Approving or disapproving of exemption applications except those involving international matters; and
5. Administering the subsidy program.

The principal reasons for this reorganization are to integrate route licensing and pricing work of the Board staff in order to encourage new and existing carriers to offer new domestic service at lower fares, and to provide primary organizational focus for planning, preparing for, and administering regulatory reform amendments to the Federal Aviation Act. In addition to processing the day-to-day work, this new responsibility will require the Bureau to advise the Board in the development of a variety of new regulatory policies and procedures needed to create more competition, reduce regulatory delays, and bring to consumers the benefits of less expensive and more widely available aviation services, principally in the domestic area.

Responsibility for international route award cases involving low fare proposals will be shared by the Bureau of Pricing and Domestic Aviation and the Bureau of International Aviation to ensure that the staff case adequately explores alternatives and reflects Board policy.

Specific delegations of authority in Part 385 are being amended in OR-141, and conforming amendments are being made to Parts 312 and 387 in PR-185 and OR-142, respectively. Substitution of the new bureau name in all other parts of the Board's regulations is effected by ER-1085. These

amendments are also being issued today.

Since these amendments are administrative in nature, affecting rules of agency organization and procedure, we find that notice and public procedure are unnecessary and that the rules may be effective immediately.

Accordingly, the Civil Aeronautics Board amends Part 384 of its Organization Regulations (14 CFR Part 384) as follows:

In § 384.7, paragraph (c) is amended, and paragraph (d) is revoked and reserved, to read:

§ 384.7 Organization and delegation of authority.

(c) The Bureau of Pricing and Domestic Aviation, which is the Board component involved in ratemaking and, except in matters involving foreign air transportation, the licensing and maintenance of proper competitive conditions among air carriers. This Bureau handles matters involving commercial passenger, baggage, and freight rates, service mail rates, subsidy rates, and military charter rates. It also handles domestic air transportation matters involving certificates, exemptions, and mergers for scheduled, charter, helicopter, and all-cargo air carriers, air taxi operators, and freight forwarders.

(d) [Reserved].

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743, (49 U.S.C. 1324); Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989, (49 U.S.C. 1324 (note)).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35685 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Reg. OR-141; Amdt. No. 77]

PART 385—DELEGATIONS AND REVIEW OF ACTION UNDER DELEGATION: NONHEARING MATTERS

Creation of Bureau of Pricing and Domestic Aviation

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., December 14, 1978.

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This rule amends the Board's delegations of authority to reflect the consolidation of the Bureau of Operating Rights and the Bureau of Fares and Rates into a new bureau,

the Bureau of Pricing and Domestic Aviation.

DATES: Effective: December 14, 1978.
Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of General Counsel, Rules Division, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C., 202-673-5442.

SUPPLEMENTARY INFORMATION: For the reasons discussed in OR-140, which is being issued simultaneously with this rule, we are amending the delegations of authority that appear in Part 385 of the Organization Regulations.

The delegations to the Director of the Bureau of Operating Rights (BOR) currently appear in § 385.13. A delegation to the Director of the Bureau of Fares and Rates (BFR) appears in § 385.14.¹ In accordance with these bureaus' replacement by the Bureau of Pricing and Domestic Aviation (BPDA), this amendment combines the two sections in a retitled § 385.13 and revokes § 385.14. All portions of the current § 385.13 retain their paragraph designations² and the delegation now in § 385.14 is added on as a new § 385.13(pp).

By virtue of § 385.7,³ the Director of BFR has also had the authority delegated to BFR division and section chiefs in §§ 385.14a, .15, .16, and .16a. The transfer of this authority to the Director of BPDA is therefore effected by merely substituting the new bureau name for "Bureau of Fares and Rates" wherever that name appears. To reflect a reorganization of the divisions and sections within BPDA, §§ 385.15 and 385.16a are being retitled. Similarly, the functions formerly exercised by the Chief, Passenger and Cargo Rates Division (§ 385.14a) and the Chief, Government Rates Division (§ 385.16) are being combined in a newly titled § 385.16, delegating authority to the Associate Director, Pricing. In connec-

¹This § 385.14 was inserted in Part 385 by OR-124, adopted December 1, 1977 (42 FR 61858, December 7, 1977). That amendment redesignated the prior § 385.14 as § 385.14a (Delegation to the Chief, Passenger and Cargo Rates Division, BFR). The consolidation of § 385.14a into § 385.16 is discussed below.

²Only § 385.13(jj) is being changed in substance. Until now it has delegated to the Director of BOR the authority to take certain tariff-related actions with the concurrence of the Director of BFR. With the functions of both directors being assumed by the Director of BPDA, the concurrence requirement becomes meaningless, and is therefore being deleted.

³§ 385.7 specifies in relevant part that a delegation to a staff member below the rank of a bureau director is also considered to be a delegation to the staff member's bureau director himself.

tion with this combination, an obsolete delegation relating to U.S. Armed Forces in South Vietnam (§ 385.14a(h)) is being deleted.

We are also updating § 385.13 in several respects. In paragraphs (d), (e), and (f), the cross references to Parts 296 and 297 are corrected to reflect the consolidation of those parts in Part 296 by ER-917 (adopted June 27, 1975, 40 FR 28079, July 3, 1975). The delegation in paragraph (v) is eliminated as unnecessary, in light of the broader delegation in paragraph (cc) to grant or deny waivers of the charter regulations when grant or denial is in accordance with established precedent. Similarly, paragraph (z) is deleted, in light of the broader exemption-granting authority found in paragraph (b). Because small jet aircraft are no longer subject to special treatment in the regulation of air taxi operations, the delegation in paragraph (x) has also become unnecessary and is therefore being deleted. An oversight is corrected by amending paragraphs (cc) and (ff) to include references to advance booking charters. Corresponding delegations to administer the new Public Charter rule, Part 380 are also added.

These amendments do not affect the functions that were transferred by OR-129⁴ to the Bureau of International Aviation. Because that amendment and other recent rules have made extensive changes to § 385.13, however, we take this occasion to republish § 385.13 in full.

Our adoption of these amendments terminates the temporary delegations of authority to the Director-Designate of BPDA set forth in Order 78-4-147.

Since these amendments are administrative in nature, affecting rules of agency practice and procedure, we find that notice and public procedure are unnecessary and the rules may be effective immediately.

Accordingly, the Civil Aeronautics Board amends Part 385 of its Organization Regulations (14 CFR Part 385) as follows:

1. The Table of Contents, Subpart B, is amended by changing the heading of § 385.13, deleting and reserving § 385.14, deleting § 385.14a, and changing the headings of §§ 385.15, and 385.16, and 385.16a, to read:

Subpart B—Delegation of Functions to Staff Members

Sec.

385.13 Delegation to the Director, Bureau of Pricing and Domestic Aviation.

385.14 [Reserved].

385.15 Delegation to the Chief, Tariffs Division, Bureau of Pricing and Domestic Aviation.

⁴Adopted July 25, 1978 (43 FR 34120, August 3, 1978).

385.16 Delegation to the Associate Director, Pricing, Bureau of Pricing and Domestic Aviation.

385.16a Delegation to the Assistant Director, Legal Analysis Division, Bureau of Pricing and Domestic Aviation.

2. In all other portions of the Table of Contents, "Bureau of Fares and Rates" is replaced by "Bureau of Pricing and Domestic Aviation" wherever it appears.

3. Section 385.13 is amended to read:

§ 385.13 Delegation to the Director, Bureau of Pricing and Domestic Aviation.

The Board delegates to the Director, Bureau of Pricing and Domestic Aviation, the authority to:

(a)(1) Approve or deny applications of certificated route air carriers for exemptions to serve a point certificated on one segment of its route in place of a point certificated on another segment of its route whenever both points are in the United States and no substantial competition to other lines will result, and to perform single flights, except flights in foreign air transportation, outside the authority contained in the certificate. This authority may not be redelegated.

(2) Approve, when no person disclosing a substantial interest protests, or deny applications of certificated route air carriers for exemptions to perform any other operation prohibited by a term, condition, or limitation in a certificate, except operations predominantly in foreign air transportation. This authority may not be redelegated.

(3) Approve or disapprove Airport Notices which indicate an intention to serve regularly a point in the United States through any airport not regularly used by a holder of a certificate of public convenience and necessity and grant or deny requests for an effective date earlier than 30 days subsequent to filing such Airport Notices unless that service will be predominantly in foreign air transportation.

(b) Approve or deny applications of direct air carriers for exemptions from section 401 of the Act and from applicable regulations under this chapter, except exemptions relating to operations that are predominantly in foreign air transportation, where the course of action is clear under current Board policies.

(c) [Reserved].

(d) Approve or disapproved applications for operating authority filed pursuant to Part 296 of this chapter (Economic Regulations); and by letter to dismiss any such application: *Provided*, That the applicant is given prior notice that his application will be dismissed, if, in appropriate cases

he does not, within 30 days, file information necessary to complete the processing of his application, or file a tariff.

(e) Approve or deny applications for approval of relationships prohibited by §§ 296.56(b) and 296.60 of this chapter (Economic Regulations).

(f) Grant or deny requests by air freight forwarders for permission to deviate from the documentation requirements of § 296.73 of this chapter (Economic Regulations). Such requests will be granted upon a due showing that the record retention system of the forwarder permits ready access to information otherwise required on a manifest; that the name of the person determining rates and charges, together with the commodity rate applied, appears on the airway bill; that the forwarder will provide copies of airwaybills to the consignor or consignee when either so requests; and that the recordkeeping operations of the forwarder otherwise comport with the policy set forth in Order E-19074 of December 7, 1962.

(g) Cancel any operating authority upon the filing by a domestic or international Air Freight Forwarder of a written notice with the Board indicating the discontinuance of common carrier activities.

(h) Approve or disapprove interchange schedules, except those involving points outside the United States. Approvals may be granted when such schedules appear to conform to the service plan contemplated by the Board's orders approving the basic interchange agreements.

(i) [Reserved].

(j) Approve or disapprove applications of certificated helicopter carriers requesting amendments of Flight Patterns operated under the carriers' area exemption authorizations.

(k) Approve or disapprove applications of air carriers for permission to do business in names other than those authorized pursuant to regulation or order of the Board.

(l) Issue revised operating authorizations and Exemption Orders, except authorization and Exemption Orders involving service predominantly in foreign air transportation, when revisions thereof are made necessary due to a change in name of the carrier specified in the document: *Provided*, That no issue of substance concerning the operating authority of a carrier is involved.

(m) In respect of service patterns:

(1) Approve or disapprove all applications filed under § 202.14 of this chapter (Economic Regulations) by local service carriers for authority to effect temporary or seasonal changes in service patterns;

(2) Approve, when no person disclosing a substantial interest protests, or

disapprove such applications to effect any other changes in service patterns;

(3) Revoke, modify or renew, prior approval of (i) temporary or seasonal changes, or (ii) in the absence of protest by third persons disclosing a substantial interest, any other changes in service patterns; and

(4) Dismiss applications for changes in service patterns when such dismissal is requested by the applicant, or when the application is moot.

(n) With respect to postponement of inauguration of service or temporary suspension of service under Part 205 of this chapter (Economic Regulations):

(1) Approve or disapprove applications for authority to postpone inauguration of new service, except service in foreign air transportation, pursuant to certificate awards; and, upon notice, modify, condition, or terminate orders authorizing postponement; and

(2) Approve or disapprove applications for authority to temporarily suspend service, except service in foreign air transportation; and, upon notice modify, condition, or terminate orders authorizing the temporary suspension of service.

(o) [Reserved].

(p) With respect to section 412 contracts and agreements:

(1) Approve contracts or agreements, or modifications, terminations, or cancellations thereof, filed by air carriers under section 412 of the Act, except:

(i) Those which are concerned with the establishment of rates, fares, or charges; or

(ii) Those protested by a person disclosing a substantial interest and which are concerned with (A) standardization of equipment; (B) schedules; (C) substantial limitations on competition; or (D) interchange of equipment and "Trackage rights"; or

(iii) Those protested by a person disclosing a substantial interest and which are industrywide or substantially industrywide in effect, other than those which there are clear Board precedents, or which do not involve substantial questions of policy.

(2) Disapprove contracts or agreements, or modifications, terminations, or cancellations thereof, filed by air carriers under section 412 of the Act, except those involving the establishment of rates, fares, or charges.

(3) Terminate matters relating to contracts and agreements (except those concerning rates, fares, or charges) which, prior to review thereof, have expired, been terminated, or been superseded.

(q) With respect to interlocking relationships: (1) Grant or deny applications for approval of interlocking relationships filed under section 409(a) of the Act; (2) dismiss applications for approval of interlocking relationships

where the termination of the interlocking relationship in question has been effected.

(r) With respect to consolidations, mergers, purchases, leases, operating contracts, and acquisitions of control:

(1) Grant or deny applications for exemption from section 408 of the Act; and

(2) Grant or deny pursuant to the third proviso of section 408(b) to the Act applications for approval of transactions which are found not to affect the control of an air carrier directly engaged in the operation of aircraft in air transportation, not to result in creating a monopoly, and not to tend to restrain competition.

(3) Approve or deny wet leases where approval or denial of the request is in accordance with established Board precedent.

(s) With respect to air carrier authority to conduct specific charter operations, other than a MAC operation or an operation predominantly in foreign air transportation:

(1) Grant or deny an air carrier such authority, imposing such conditions as exclusion of one-way passengers or limitations on payments for labor in arranging the charter; and approve or disapprove minor changes prior to flight date in charters previously authorized by order (e.g., changes regarding flight dates, departure or landing points, aircraft, persons authorized for one-way passage, intermingling of passengers, or substituting another carrier in cases of emergency).

(2) Grant or deny requests for exemption from section 403 of the Act, where grant or denial of the request is in conjunction with and incident to requests for authority under paragraph (s)(1) of this section.

(t) Waive the provisions of § 377.10(c) of this chapter (Special Regulations) with respect to the time for filing applications for the renewal of temporary authorizations, except temporary authorizations to perform operations that are predominantly in foreign air transportation, so as to permit their filing within shorter periods than required by that section when, in his judgment, the public interest would be thereby served: *Provided*, That the interim extension provisions of § 377.10(d) of this chapter shall, if otherwise pertinent, apply to authorizations involved in applications filed pursuant to such waivers.

(u) [Reserved]

(v) [Reserved]

(w) Approve applications for authority to file pickup and delivery tariffs under Part 222 where approval of the application is in accordance with established Board precedent.

(x) [Reserved]

(y) [Reserved]

(z) [Reserved]

(aa) [Reserved]

(bb) [Reserved]

(cc) Grant or deny requests for waiver of Parts 207, 208, 212, 214, 371, 372, 372a, 373, 378, 378a, and 380 of this chapter, where grant or denial of the request is in accordance with established Board precedent.

(dd) Approve or disapprove escrow agreements filed pursuant to §§ 207.17, 208.40, 212.15 and 214.9c, respectively, of this chapter by certificated route air carriers, charter air carriers, foreign route air carriers, and foreign charter air carriers, respectively, as security for customers' deposits made with such carriers as advance payment for charter flights.

(ee) Grant or deny requests for waiver of §§ 207.25, 208.202b, 212.25, and 214.18 of this chapter (Economic Regulations), based upon a showing that the arrangements between the chartering organization and the charter participants do not involve the provision of return transportation to the United States.

(ff) Reject or accept filings made with respect to advance booking charters, travel group charters, study group charters, inclusive tour charters, and one-stop-inclusive tour charters, pursuant to §§ 371.25(a)(1), 372a.22(a), 373.10(b), 378.10(a), and 378a.25(a)(1), respectively, and to permit amended filings reflecting changes to such advance booking charters, study group charters, inclusive tour charters, and one-stop-inclusive tour charters, to become effective prior to the expiration of the 15-day waiting period prescribed by §§ 371.25(a)(2), 373.10(b), 378.10(b) and 378a.25(a)(2), respectively.

(gg) Reject or accept Public Charter prospectuses in accordance with § 380.25, and permit amended prospectuses to become effective before the end of the waiting period prescribed in that section.

(hh) Approve or deny applications of air carriers for exemptions from the provisions of section 405(b) of the Act and § 231.5(b) of Part 231 of the Economic Regulations to the extent necessary to permit the filing of schedules pursuant to section 405(b) on less than ten (10) days' notice to the Postmaster General and to the Board, except when the operations are predominantly in foreign air transportation.

(ii) Grant or deny applications for a Statement of Authorization to operate special event charters pursuant to § 378a.107.

(jj) Approve or deny applications for exemption from section 403 of the Act to the extent necessary to permit performance of air carrier operations otherwise authorized by exemption granted under subparagraphs (a)(1) and (a)(2), and paragraph (b) of this sec-

tion. This authority may not be redelegated.

(kk) Dismiss applications filed under §§ 302.1301-1315 and §§ 302.1401-1415, without prejudice to refiling in amended form or under the normal certificate procedure, if the application is not in compliance with the provisions of these sections.

(ll) With respect to interaffiliate transactions with or affecting the air carrier, and revisions, refilings, renewals or amendments thereto, which have been filed pursuant to a Board order permitting such intercompany transactions unless after such filing, an order is issued disapproving or deferring action in whole or in part with respect to such filings, within a period of thirty days:

(1) By inaction permit such intercompany transaction to become effective thirty days after such filing;

(2) Issue orders disapproving in whole or in part such intercompany transaction;

(3) Issue orders deferring in whole or in part such intercompany transaction; and

(4) For good cause shown, waive the thirty-day effectiveness date of such interaffiliate transaction: *Provided, however*, That such waiver does not extend beyond the filing date of the intercompany transaction: *And provided, further*, That this authority shall not extend to interaffiliate transactions which involve dividends, loans and advances, tax allocations, and corporate reorganizations or acquisitions.

(mm) [Reserved]

(nn) Grant or deny, in accordance with established Board precedent, applications for relief, under section 101(3) of the Act, to hold out, arrange, and coordinate the operation of air ambulance flights as indirect air carriers.

(oo) Require pickup and delivery tariffs to be filed with the Board under Part 221 of the Economic Regulations by carriers operating in domestic cargo transportation under Part 291, if in the public interest.

(pp) Under section 410 of the Act, approve or disapprove in whole or in part, or make recommendations requested by any Federal agency with respect to, applications by air carriers for loans and other financial aid.

§ 385.14 [Reserved]

4. Section 385.14 is revoked and reserved.

§ 385.14a [Revoked]

5. Section 385.14a is revoked.

6. Section 385.15 is redesignated and its first sentence is amended to read:

§ 385.15 Delegation to the Chief, Tariffs Division, Bureau of Pricing and Domestic Aviation.

The Board delegates to the Chief, Tariffs Division, Bureau of Pricing and Domestic Aviation, the authority to:

7. Section 385.16 is redesignated, its first sentence is amended, and paragraphs (k) through (r) are added, to read:

§ 385.16 Delegation to the Associate Director, Pricing, Bureau of Pricing and Domestic Aviation.

The Board delegates to the Associate Director, Pricing, Bureau of Pricing and Domestic Aviation, the authority to:

(k) With respect to International Air Transport Association (IATA) agreements filed with the Board pursuant to section 412 of the Act or pursuant to Board Order E-9305 of June 15, 1955:

(1) Disclaim jurisdiction with respect to IATA agreements which do not affect air transportation within the policy set forth in Order E-12304, dated March 31, 1958;

(2) Approve agreements which do not directly apply in air transportation;

(3) Issue orders approving, disapproving, or approving subject to conditions, IATA agreements relating to fare and rate matters, other than those establishing fares and rates directly applicable in air transportation as agreed at regular and special traffic conferences, with respect to the following:

(i) Agreements naming additional specific commodity rates (rates below general cargo rates) under new, existing, or amended descriptions; amending descriptions; and/or extending or canceling existing specific commodity rates.

(ii) Agreements reached by unprotected notice pursuant to previously approved resolutions.

(iii) Agreements establishing or amending proportional or constructed fares or rates.

(iv) Agreements naming specified fares or rates to be integrated into previously approved fare or rate structures.

(v) Agreements amending or extending application of construction rules.

(vi) Agreements amending application of special (reduced) fare resolution provisions.

(vii) Agreements providing for delays in inaugurals.

(viii) Agreements establishing, amending, or terminating charges for

nontransportation services and other ancillary fare or rate agreements involving administrative, procedural, or technical provisions, not affecting fare or rate levels.

(ix) Agreements establishing, amending, or terminating a surcharge or discount on foreign-originating air transportation to reflect a currency fluctuation.

(4) Issue orders describing filed agreements, establishing procedural dates for submission of justification, comments and replies, which support or oppose agreements, and prescribing the particular types of data to be included in such submissions.

(l) Approve or disapprove air carrier applications filed under section 416(b) of the Act for exemption from section 403 of the Act, air carrier tariffs, and applicable Board regulations, in cases where the disposition of the application is governed by established Board policy and precedent. Such approval or disapproval may be taken by order, by letter, or by stamp or notation on a copy of the application.

(m) Approve or disapprove applications requesting relief from requirements of Board orders that carriers file data relating to experience under new rates and fares.

(n) Approve or disapprove applications for permission to furnish free or reduced-rate air transportation to travel agents.

(o) Approve or disapprove applications for permission to furnish free or reduced-rate air transportation to instructors and travel agent organization employees in connection with travel agent training programs to which travel agents are accorded free or reduced-rate air transportation.

(p) Approve or disapprove applications for permission to furnish free or reduced-rate air transportation to commissioned and enlisted military personnel when on official business of an air carrier to which they have been assigned for educational training purposes.

(q) Approve or disapprove written statements filed by air carriers pursuant to § 250.9 of this chapter (Economic Regulations) explaining the terms, conditions, and limitations of denied boarding compensation provided by Part 250 of this chapter.

(r) Maintain, issue, and distribute lists of all carrier parties to Agreement 18900 (Montreal Agreement) providing for increased liability limitations on personal injury or death and waiver of defenses under Article 20(1) of the Warsaw Convention or the Hague Protocol.

8. Section 385.16a is redesignated and its first sentence is amended to read:

§ 385.16a Delegation to the Assistant Director, Legal Analysis Division, Bureau of Pricing and Domestic Aviation.

The Board delegates to the Assistant Director, Legal Analysis Division, Bureau of Pricing and Domestic Aviation, the authority to:

§ 385.26 [Amended]

9. In § 385.26(c), "Tariffs Section" is replaced by "Tariffs Division".

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743 (49 U.S.C. 1324); Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989 (49 U.S.C. 1324 (note)).)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc 78-35686 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Reg. OR-142; Amdt. No. 8]

PART 387—ORGANIZATION AND OPERATION DURING THE PERIOD OF A NATIONAL EMERGENCY

Miscellaneous Amendments

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., December 14, 1978.

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This rule revises the order of succession to Board Members during national emergencies, to reflect the consolidation of the Bureau of Fares and Rates and the Bureau of Operating Rights into a new Bureau of Pricing and Domestic Aviation. It also substitutes the position of Executive Assistants to the Managing Director for the position of Deputy Managing Director, and updates the citation of authority for this part.

DATES: Effective: December 14, 1978. Adopted: December 14, 1978.

FOR FURTHER INFORMATION CONTACT:

Mark Schwimmer, Office of General Counsel, Rules Division, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C., 202-673-5442.

SUPPLEMENTARY INFORMATION: Part 387 describes the organization and operation of the Board during periods of national emergency. The lines of succession to the authority of the Board and of the Chairman are set out in § 387.4. In the current version of the rule, the Director of the Bureau of Fares and Rates (BFR) precedes the General Counsel, who in turn precedes

the Director of the Bureau of Operating Rights (BOR).

As reflected in OR-140, which is also being issued today, BFR and BOR have been consolidated into a new Bureau of Pricing and Domestic Aviation. This rule amends the lines of succession so that the Director of the new bureau will precede the General Counsel.

In the succession to the Managing Director, this rule substitutes the Executive Assistant to the Managing Director for the Deputy Managing Director, because the latter position no longer exists.

Part 387 was originally issued under the authority of Executive Order 11090 (February 26, 1963). That Executive Order was revoked and replaced by Executive Order 11490 (October 28, 1969), which was in turn amended by Executive Order 11921 (June 11, 1976). While the authority citation issued with a Board regulation is not a part of the regulation itself, it is useful to those who wish to review the legislative background of the rule-making action. This amendment therefore updates Part 387's authority citation so that it may serve researchers more effectively.

This rule also corrects an oversight in the original drafting of § 387.4(d), by replacing "if any Board Member is unable to act as Chairman" with "if no Board member is able to act as Chairman".

Since these amendments are administrative in nature, affecting rules of agency organization and procedure, we find that notice and public procedure are unnecessary and that the rules may be effective immediately.

Accordingly, the Civil Aeronautics Board amends Part 387 of its Organization Regulations (14 CFR Part 387) as follows:

1. The authority citation is amended to read as set forth below.

2. Paragraphs (c), (d), and (g) of § 387.4 are amended to read:

§ 387.4 Organization and delegation of authority.

During a national emergency:

(c) In the event no Board Member is capable of acting, actions in the name and authority of the Board shall be taken by the following: The Managing Director; the Director, Bureau of Pricing and Domestic Aviation; the General Counsel; and the Director, Bureau of Consumer Protection. If one or more of them cannot act, his or their deputies or staff in line of succession

as provided in paragraph (g) of this section shall act. The authority of the above designees, or their successors, shall mean and include the delegated authority to act for the Board.

(d) The authority of the Chairman, in the event he is incapacitated or incapable of acting, shall be exercised by the Vice Chairman, and in the event he is unable to act, by the other Members of the Board in order of seniority; if no Board Member is able to act as Chairman, then members of the Board's staff shall act as Chairman in the following order: The Managing Director; the Director, Bureau of Pricing and Domestic Aviation; the General Counsel; the Director, Bureau of Consumer Protection; their respective deputies or staff in line of succession to the preceding staff members.

(g) Except as may be determined otherwise by the Chairman or his successor, the respective duties of the Managing Director shall be filled by the Executive Assistant to the Managing Director or the Comptroller in that order; the duties of the Secretary and heads of offices and bureaus, and heads of field offices, shall be discharged, in the absence or incapacity of such persons during the emergency conditions, by the available staff member next in line of succession in that office or bureau. The head of each office and bureau shall designate the line of succession within his office or bureau. If no such designation has been made, or the designee is unavailable, such duties shall be assumed by the available subordinate officer or employee in the particular office or bureau who is highest in grade and has served longest with the Board.

(Sec. 204(a), Federal Aviation Act of 1958, as amended, 72 Stat. 743, (49 U.S.C. 1324; sec. 201, National Emergencies Act, 90 Stat. 1255, Reorganization Plan No. 3 of 1961, 75 Stat. 837, 26 FR 5989, (49 U.S.C. 1324 (note)); E.O. 11490, 3 CFR 1966-1970 Comp. p. 820, as amended by E.O. 11921, 3 CFR 1976 Comp. p. 124)

By the Civil Aeronautics Board.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35687 Filed 12-21-78; 8:45 am]

[3510-07-M]

Title 15—Commerce and Foreign Trade

CHAPTER I—BUREAU OF THE CENSUS, DEPARTMENT OF COMMERCE

PART 50—SPECIAL SERVICES AND STUDIES BY THE BUREAU OF THE CENSUS

Fee Structure for Statistics for City Blocks in the 1980 Census of Population and Housing; Clarification

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Final rule.

SUMMARY: This document clarifies a Notice of Rulemaking which appeared at 43 FR 3903 on January 30, 1978. That notice adopted a final rule relating to the tabulating and publishing of block data for each urbanized area in the United States and for each incorporated place over 10,000 inhabitants. This notice clarifies the notice of January 30, 1978, by adding, at the end thereof, an appropriate citation of authority.

EFFECTIVE DATE: This notice is retroactively effective to January 30, 1978.

FOR FURTHER INFORMATION CONTACT:

Arthur F. Young, Chief, Housing Division, Bureau of the Census, Washington, D.C. 20233 (301) 763-2863.

SUPPLEMENTARY INFORMATION: Supplementary information concerning the rule issued on January 30, 1978, accompanies the rule in the FEDERAL REGISTER for that date, at page 3903.

CLARIFICATION OF PRIOR NOTICE: The notice of rulemaking appearing in volume 43 of the FEDERAL REGISTER at page 3903 is hereby amended by adding as a new final paragraph, the following:

(Sec. 8, title 13, United States Code.)

Dated: December 18, 1978.

MANUEL D. PLOTKIN,
Director,
Bureau of the Census.

[FR Doc. 78-35570 Filed 12-21-78; 8:45 am]

[6740-02-M]

Title 18—Power and Water Resources**CHAPTER I—FEDERAL ENERGY REGULATORY COMMISSION,¹ DEPARTMENT OF ENERGY**

[Docket No. RM79-3]

PUBLIC HEARINGS ON INTERIM REGULATIONS IMPLEMENTING THE NATURAL GAS POLICY ACT OF 1978

DECEMBER 20, 1978.

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Notice of the Public Hearings on Interim Regulations Implementing the Natural Gas Policy Act of 1978.

SUMMARY: The Federal Energy Regulatory Commission (the Commission) gives notice that it will hold public hearings at New Orleans, Louisiana, San Francisco, California, New York, New York, and Washington, D.C. and invites oral presentations on the interim regulations implementing the Natural Gas Policy Act of 1978, 43 FR 56448 (December 1, 1978).

DATES: Public hearings at New Orleans, Louisiana, and San Francisco, California; Date for public hearings: January 3, 1979, to be continued, if necessary, January 4, 1979; Date for requests to participate: December 27, 1978.

Public hearing at New York, New York: Date for public hearing: January 10, 1979, to be continued, if necessary, January 11, 1979; Date for request to participate: January 3, 1979.

Public hearing at Washington, D.C.: Date for public hearing: January 25, 1979, to be continued, if necessary on January 26, 1979; date for requests to participate: January 17, 1979.

ADDRESSES:*New Orleans:* Fifth Circuit Court of Appeals Building, Room 105, 600 Camp Street, New Orleans, Louisiana.*San Francisco:* Delores Room of the Hyatt Union Square Hotel, 345 Stockton, San Francisco, California.*New York City:* Room 770, Six World Trade Center, New York, New York.*Washington:* 825 North Capitol Street NE., Washington, D.C.**FOR FURTHER INFORMATION:**

Robert L. Baum, Deputy General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, (202) 275-4333.

¹[18 CFR Parts 2, 157, 270, 271, 273, 274, 275, 276 and 284]

SUPPLEMENTARY INFORMATION: Section 502(b) of the Natural Gas Policy Act of 1978 requires that the Commission, to the maximum extent practicable, afford an opportunity for oral presentation of data, views, and arguments with respect to any rules promulgated by the Commission pursuant to the Natural Gas Policy Act of 1978 (Act).

The Commission has previously notified the public of one public hearing on the Interim Regulations, to be held on December 27, 1978, which is within 30 days of the effective date of the regulations (43 FR 59056, December 19, 1978). The purpose of this notice is to inform interested persons of the Commission's intention to conduct additional public hearings regarding the Interim Regulations promulgated pursuant to the Act (43 FR 56448).

PUBLIC HEARING PROCEDURES

The Commission will hold four additional public hearings in this proceeding. On Wednesday, January 3, 1979, beginning at 9:30 a.m., hearings will be held in the Fifth Circuit Court of Appeals Building, Room 105, 600 Camp Street, New Orleans, Louisiana, and the Delores Room of the Hyatt Union Square Hotel, 345 Stockton, San Francisco, California. These hearings will continue on Thursday, January 4, 1979, if necessary. On Wednesday, January 10, 1979, beginning at 9:30 a.m., a hearing will be held in Room 770, Six World Trade Center, New York, New York. These hearings will continue on Thursday, January 11, 1979, if necessary. The final hearing will be held in Washington, January 25, 1979 continuing, if necessary, on January 26, at 825 North Capitol Street NE., Washington, D.C.

Any person interested in these proceedings or representing a group or class of persons interested in these proceedings may participate in the hearings, if a telephone or written request to participate is made to Robert L. Baum prior to 4:30 p.m., December 27, 1978 for the January 3 hearing, prior to 4:30 p.m., January 3 for the January 10 hearing, and prior to 4:30 p.m., January 17, 1979 for the January 25 hearing.

Requests to participate at a hearing should state the hearing for which time is requested, and include a reference to Docket No. RM79-3 and a number where the person making the request may be reached by telephone. Persons participating in the public hearing should, if possible, bring 100 copies of their testimony to the hearing. The presiding officer is authorized to limit oral presentations at the hearing both as to length and as to substance.

The hearing will not be a judicial or evidentiary-type hearing. There will

be no cross-examination of persons presenting statements. The hearing panel may question such persons and any interested person may submit questions to the presiding officer to be asked of persons making statements. The presiding officer will determine whether the question is relevant and whether the time limitations permit it to be presented. At the conclusion of the initial oral presentations, if time permits, persons who have participated will be given the opportunity to make rebuttal statements. Any further procedural rules will be announced by the presiding officer at each hearing. A transcript of the hearings will be made available at the Commission's Office of Public Information.

By direction of the Commission.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35829 Filed 12-21-78; 8:45 am]

[4510-30-M]

Title 20—Employees' Benefits**CHAPTER V—EMPLOYMENT AND TRAINING ADMINISTRATION, DEPARTMENT OF LABOR****PART 614—UNEMPLOYMENT COMPENSATION FOR EX-SERVICEMEN****New Schedule of Remuneration**

AGENCY: Employment and Training Administration, Labor.

ACTION: Final rule.

SUMMARY: The Department of Labor is amending 20 CFR 614.19, to increase the monthly rates of remuneration in the Schedule of Remuneration used to compute the Federal wages of ex-servicemen and women covered by the program of Unemployment Compensation for Ex-Servicemen (UCX Program). The new schedule will apply to new claims that are filed on and after January 1, 1979.

EFFECTIVE DATE: January 1, 1979, with respect to first claims filed on and after that date.

FOR FURTHER INFORMATION CONTACT:

Robert B. Edwards, Acting Administrator, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, 601 "D" Street NW., Washington, D.C. 20213, telephone: 202-376-7032.

SUPPLEMENTARY INFORMATION: Section 8521(a)(2) of Chapter 85, Title 5 of the United States Code (5 U.S.C. 8521(a)(2)) requires the Secretary of Labor to issue, from time to time,

after consultation with the Secretary of Defense, a Schedule of Remuneration specifying the pay and allowances for each pay grade of members of the military services, which reflect representative amounts for appropriate elements of the pay and allowances whether in cash or in kind.

The new Schedule of Remuneration amended in this document adjusts the scheduled monthly rates of pay upward to reflect the military pay increase that became effective on October 1, 1978, under Executive Order 12087. The new schedule set forth in this document is effective with respect to first claims which are filed after the end of this year; that is, new claims filed on and after January 1, 1979. Although the effective date will necessitate making the new schedule effective less than 30 days after this publication, the reasons for making the new schedule effective at the beginning of 1979 are believed to be overriding.

This revision of § 614.19 of Title 20 of the Code of Federal Regulations was published as a proposal with opportunity for public participation of 43 FR 49545 on October 24, 1978, with a comment period ending on November 24, 1978. No comments were received and no changes are made in the revision as proposed.

NOTE.—The Department of Labor has determined that the revision in this document will not have major economic effects requiring the preparation of a regulatory analysis under Executive Order 12044 and applicable authority.

This document was prepared under the direction and control of Robert B. Edwards, Acting Administrator, Unemployment Insurance Service, Employment and Training Administration, U.S. Department of Labor, 601 "D" Street NW., Washington, D.C. 20213, telephone: 202-376-7032.

Accordingly, § 614.19 of Chapter V of Title 20 is revised to read as follows:

§ 614.19 Schedule of Remuneration.

(a) The following Schedule of Remuneration is issued pursuant to 5 U.S.C. 8521(a)(2), and shall apply to first claims which are filed after December 31, 1978:

Pay Grade	Monthly rate
(1) Commissioned officers:	
O-10	\$4,973
O-9	4,969
O-8	4,678
O-7	4,129
O-6	3,412
O-5	2,797
O-4	2,307
O-3	1,935
O-2	1,535
O-1	1,142
(2) Warrant officers:	
W-4	2,184
W-3	1,757
W-2	1,527
W-1	1,332

Pay Grade	Monthly rate
(3) Enlisted personnel:	
E-9	1,873
E-8	1,614
E-7	1,393
E-6	1,177
E-5	995
E-4	845
E-3	754
E-2	706
E-1	645

(b) The Schedule of Remuneration published at 42 FR 65483 remains applicable to first claims filed prior to the effective date of the new Schedule of Remuneration set forth in paragraph (a) of this section. The new schedule in paragraph (a) does not revoke the prior schedule or any preceding schedule or change the periods of time they were in effect.

(5 U.S.C. 8508, 8521(a)(2).)

Signed at Washington, D.C., on December 14, 1978.

ERNEST G. GREEN,
Assistant Secretary for
Employment and Training.

[FR Doc. 78-35517 Filed 12-21-78; 8:45 am]

[1505-01-M]

Title 21—Food and Drugs

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

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

Hydrochlorothiazide Injection
Correction

In FR Doc. 78-35044 appearing on page 59057 in the issue for Tuesday, December 19, 1978, the EFFECTIVE DATE should read "December 19, 1978."

[4710-06-M]

Title 22—Foreign Relations

CHAPTER I—DEPARTMENT OF STATE

[Dept. Reg. 108.763]

PART 41—DOCUMENTATION OF NONIMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

PART 42—DOCUMENTATION OF IMMIGRANTS UNDER THE IMMIGRATION AND NATIONALITY ACT, AS AMENDED

Miscellaneous Amendments

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: Title 22 CFR 42.111 (c)(2), which now requires that a consular officer's statement regarding the unavailability of a document for immigrant visa purposes must contain the seal of his office, is amended to delete this requirement as unnecessary. Section 41.122 is editorially amended to change the title to emphasize the existence therein of the termination of validity provision as distinct from the revocation provision located in § 41.134.

EFFECTIVE DATE: December 22, 1978.

SUPPLEMENTARY INFORMATION: Since a consular officer's statement concerning the unavailability of a document is attached to a properly executed visa application, which is in turn securely fastened to and becomes part of the signed and sealed immigrant visa, the presence of an additional seal on the statement serves no useful purpose. The title change in § 41.122 is purely editorial and more clearly explains the subject matter of the regulation. Accordingly, §§ 41.122 and 42.111 are amended as indicated.

1. The present title in § 41.122 is changed to "Validity, Termination and Replacement of Visas."

2. In § 42.111(c)(2) on the ninth and tenth line "and the seal of his office" is deleted.

AUTHORITY: These amendments are issued pursuant to the authority contained in section 104 of the Immigration and Nationality Act (8 U.S.C. 1104). Compliance with section 553 of Title 5 of the United States Code as to notice of proposed rulemaking and delayed effective date is unnecessary in this instance because the amendment to § 42.111 is an internal administrative change having no effect upon the public and the amendment to § 41.122 is in the nature of an editorial clarification.

Dated: December 4, 1978.

BARBARA M. WATSON,
Assistant Secretary for
Consular Affairs.

[FR Doc. 78-35581 Filed 12-21-78; 8:45 am]

[4210-01-M]

Title 24—Housing and Urban Development

CHAPTER II—ASSISTANT SECRETARY FOR HOUSING—FEDERAL HOUSING COMMISSIONER, DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. R-78-594]

PART 200—INTRODUCTION

Requirements for Acceptance of Loose Fill Insulation Pneumatically Installed (Dry) in Wall Cavities for HUD Minimum Property Standards

AGENCY: Office of Assistant Secretary for Housing—Federal Housing Commissioner, (HUD).

ACTION: Final Rule.

SUMMARY: The Assistant Secretary for Housing-Federal Housing Commissioner establishes as acceptable a settling density of 3.5 lb./cu. ft. for installation of dry loose fill insulation pneumatically installed in wall cavities. This is necessary to permit the use of such insulation in walls. According to our current criteria, cellulosic insulation may be installed dry in horizontal locations such as attics. It is not acceptable for walls because no standard for settling density has been established to assure that voids do not occur. It is now generally agreed that an installation density of 3.5 lb./cu. ft. is adequate to eliminate the problem of voids which would reduce the effectiveness of an installation's energy conservation qualities.

This rule is being issued as a Final Rule to reduce delays in residential construction due to shortages of alternative insulation material. Use of the large available quantities of cellulosic insulation would reduce construction costs and yield increases in housing construction and savings to builders and home buyers.

EFFECTIVE DATE: January 22, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. Mervin Dizenfeld, Mechanical Engineer, Minimum Property Standards Division, Office of Architecture and Engineering Standards, Department of Housing and Urban Development, Washington, D.C. 20411, telephone (202) 755-6590.

SUPPLEMENTARY INFORMATION: HUD Minimum Property Standards are published in handbooks: Minimum Property Standards for One- and Two-Family Dwellings in Handbook 4900.1, Multifamily Dwellings in Handbook 4910.1, and Care-Type Housing in

Handbook 4920.1. The Minimum Property Standards are incorporated by references into 24 CFR 200.929. Notices of changes in the Minimum Property Standards are required by 24 CFR 200.933 to be published in the FEDERAL REGISTER. A Finding of Inapplicability respecting the National Environmental Policy Act of 1969 has been made in accordance with HUD procedures. A copy of this Finding of Inapplicability will be available for public inspection during regular business hours in the Office of the Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

The changes are as follows: (Existing MPS requirements not reviewed here are to remain unchanged).

507-3.2 Labeling

c. Blowing or Pouring Type. Name, manufacturer, recommended installation density, R value, marking on bag in conformance with appropriate standards listed in Appendix C.

507-3.3 Certification

A certification card giving the data of 507-3.2a, b, c or d and 507-3.4c plus date of installation, and the name of the installer shall be affixed to the structure in an accessible but inconspicuous location.

507-3.4 Conditions of Use

d. Loose fill cellulosic insulation pneumatically installed in wall cavities shall (1) be blown-in dry in accordance with the manufacturer's written instructions and shall comply with FS HH-1-515D as amended for conformance with PL 95-319 and (2) the R value shall be based on an installed density (ID) of not less than 3.5 lb./cf. ID is the product of the volume (v) of the wall cavity to be filled and the weight (w) of the insulation material from the label on the container. ID equals (v) × (w) shall equal or exceed 3.5 lb./cf.

In accordance with section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this rule has been granted waiver of Congressional review requirements in order to permit it to take effect on the date indicated.

Issued at Washington, D.C., December 4, 1978.

LAWRENCE B. SIMONS,
Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 78-35694 Filed 12-21-78; 8:45 am]

[4510-26-M]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1903—INSPECTIONS, CITATIONS AND PROPOSED PENALTIES

Objections to Inspection

AGENCY: Occupational Safety and Health Administration, Department of Labor.

ACTION: Procedural Rule.

SUMMARY: This amendment to 29 CFR 1903.4 clarifies the existing regulation respecting the legal action to be taken to permit inspection of a workplace over an employer's objection. Specifically, the revised regulation makes it clear that the term "compulsory process" as used in the regulation has been, and is, intended to include all legal action necessary to secure entry to the workplace, including *ex parte* application for an inspection warrant or its equivalent. The amendment also makes plain that compulsory process, as so defined, may be secured prior to an employer's objection to an inspection or investigation. The procedures for taking appropriate action to obtain entry have also been modified to promote administrative convenience.

EFFECTIVE DATE: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. James Foster, Office of Public Affairs, Occupational Safety and Health Administration, Third Street and Constitution Avenue N.W., Room N-3641, Washington, D.C. 20210 (Tel. No. 202-523-8151).

SUPPLEMENTARY INFORMATION: Section 8(a) of the Act provides:

In order to carry out the purposes of this Act, the Secretary, upon presenting appropriate credentials to the owner, operator, or agent in charge, is authorized: (1) To enter without delay and at reasonable times any factory, plant, establishment, construction site, or other area, workplace or environment where work is performed by an employee of an employer; and (2) to inspect and investigate during regular working hours and at other reasonable times and within reasonable limits and in a reasonable manner, any such place of employment and all pertinent conditions, structures, machines, apparatus, devices, equipment, and materials therein, and to question privately any such employer, owner, operator, agent or employee.

This provision was recently examined by the United States Supreme Court in *Marshall v. Barlow's, Inc.*, 98

S. Ct. 1816 (1978). In that case the Court held section 8(a) unconstitutional insofar as it purports to authorize warrantless nonconsensual inspections, but construed the Act to permit inspection pursuant to an employer's consent or a judicially authorized search warrant or its equivalent.

In so doing the Court noted that "the Act *** regulates a myriad of safety details that may be amendable to speedy alteration or disguise" and recognized "[t]he risk *** that during the interval between an inspector's initial request to search a plant and his procuring a warrant following the owner's refusal of permission, violations of this *** type could be corrected and thus escape the inspector's notice." However, the Court did not view this risk as sufficient to justify inspection without a warrant, noting that "the advantages of surprise would [not] be lost, if after being refused entry, procedures were available for the Secretary to seek an *ex parte* warrant and to reappear at the premises without further notice to the establishment being inspected." Moreover the Court also noted that "[i]nsofar as the Secretary's statutory authority is concerned, a regulation expressly providing that the Secretary could proceed *ex parte* to seek a warrant or its equivalent would appear to be as much within the Secretary's power as the regulation [29 CFR 1903.4] currently in force and calling for compulsory process." In originally promulgating this regulation, the agency had intended the phrase "compulsory process" to include any appropriate action necessary to compel entry to a workplace. Indeed, agency representatives routinely sought and received *ex parte* warrants as one of the means for securing entry to workplaces before the *Barlow's* decision. However, since a question has been raised as to the meaning of the regulation, and in order to remove any doubt on this important matter, the regulation is being amended to make explicit that the Secretary is authorized to obtain *ex parte* warrants or their equivalent.

The *Barlow's* Court also acknowledged that *ex parte* warrants issued in advance might become necessary in order to carry out the surprise inspections which the Court recognized are specifically contemplated by the Act. However, the Court's decision raises questions as to whether the Secretary's present regulation and the Field Operations Manual provide for the obtaining of compulsory process in advance of an employer's refusal. Thus, again to remove any doubt, the present regulation is amended to expressly state that the agency's authority to obtain inspection warrants is not dependent on an employer's prior refusal to permit an inspection. In other

words, the agency may obtain warrants in advance of an inspection or investigation if such procedure is desirable or necessary under the circumstances. For example, a pre-refusal warrant for an inspection may be desirable in view of geographical factors or in situations where it is possible to predict that a refusal or other interference with the conduct of an inspection is likely.

Finally, the regulation is amended to authorize the Regional Administrator and the Regional Solicitor to institute procedures, as experience in obtaining warrants is gained, whereby compliance personnel may appear before magistrates or judges and seek warrants under the direction of the Regional Solicitor. Where instituted, such procedures will result in the conservation of Regional Solicitor resources and may also result in greater expedition in securing warrants. The regulation is also amended by deleting the requirement that the Area Director's consultation with the Regional Solicitor be "immediate" and that the Regional Solicitor's initiation of appropriate action be "prompt." This amendment is made in order to reflect that although it continues to be agency policy to minimize the delay between a refusal and the obtaining of compulsory process, discretion must be left to the Area Director and the Regional Solicitor to assign the appropriate priority to such cases.

This amendment is made pursuant to section 8(g)(2) of the Act (29 U.S.C. 657) and Secretary of Labor's Order No. 8-76 (41 FR 25059), in implementation of the general inspection and investigation authority conferred by section 8(a) of the Act. General notice of proposed rulemaking, public participation therein and delay in effective date are not required by 5 U.S.C. 553, since this section is an interpretive rule, general statement of policy and rule of agency procedure and practice.

In accordance with the above, 29 CFR 1903.4 is hereby revised to read as follows:

§ 1903.4 Objection to inspection.

(a) Upon a refusal to permit a Compliance Safety and Health Officer, in exercise of his official duties, to enter without delay and at reasonable times any place of employment or any place therein, to inspect, to review records, or to question any employer, owner, operator, agent, or employee, in accordance with § 1903.3, or to permit a representative of employees to accompany the Compliance Safety and Health Officer during the physical inspection of any workplace in accordance with § 1903.8, the Compliance Safety and Health Officer shall terminate the inspection or confine the inspection to other areas, conditions,

structures, machines, apparatus, devices, equipment, materials, records, or interviews concerning which no objection is raised. The Compliance Safety and Health Officer shall endeavor to ascertain the reason for such refusal, and shall immediately report the refusal and the reason therefor to the Area Director. The Area Director shall consult with the Regional Solicitor, who shall take appropriate action, including compulsory process, if necessary.

(b) Compulsory process may be sought in advance of an inspection or investigation if, in the judgment of the Area Director and the Regional Solicitor, circumstances exist which make preinspection process desirable or necessary.

(c) With the approval of the Regional Administrator and the Regional Solicitor, compulsory process may also be obtained by the Area Director or his designee.

(d) For purposes of this section, the term compulsory process shall mean the institution of any appropriate action, including *ex parte* application for an inspection warrant or its equivalent.

(Secs. 8(a), 8(g) Pub. L. 91-596, 84 Stat. 1600 (29 U.S.C. 657)).

Signed at Washington, D.C., this 15th day of December 1978.

EULA BINGHAM,
Assistant Secretary
of Labor.

[FR Doc. 78-35664 Filed 12-21-78; 8:45 am]

[6560-01-M]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER C—AIR PROGRAMS

[FRL 1011-5]

PART 55—ENERGY RELATED AUTHORITY

Delayed Compliance Order for Avtex Fibers Inc.

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: This notice announces that the Environmental Protection Agency (EPA) is issuing an administrative order to the Avtex Fibers Inc. requiring its Boiler Numbers one (1), two (2), and three (3) at Front Royal, Virginia to achieve compliance by June 30, 1980 with air pollution requirements under the Virginia State Implementation Plan.

EFFECTIVE DATE: December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Bernard E. Turlinski, Regional Energy Coordinator, U.S. Environmental Protection Agency, Region III, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106 (215-597-8176).

SUPPLEMENTAL INFORMATION:

EPA has developed an administrative order which is being issued under Section 113(d)(5) of the Clean Air Act ("the Act"), 42 U.S.C. 7491 et seq., to Avtex Fibers Inc. requiring its Boiler Numbers one (1), two (2), and three (3) at Front Royal, Virginia to achieve compliance with Virginia State Air Pollution Control Board, Section IV, Rules 2 and 3 of the Virginia State Implementation Plan by June 30, 1980. This order requires that Avtex Fibers Inc. install control equipment according to the schedule set forth below, prescribes interim emission reduction requirements, specifies emission limitations, prescribes coal pollutant characteristics, and requires monitoring and reporting of air quality and air pollutant emissions data. Compliance with the terms of the order precludes any further enforcement by the EPA under Section 113 of the Act and any citizens suits under Section 304 of the Act against the source for violations of the Virginia State Implementation Plan provisions covered by the order.

The entire contents of the order were proposed in the FEDERAL REGISTER on May 15, 1978 (43 FR 20823). In this notice the EPA invited the public to submit written comments on and requests for a public hearing concerning the order and its issuance.

Comments were offered only by Avtex Fibers Inc. which, for the most part, were suggested wording changes for purposes of clarity to minimize any future misunderstandings between EPA and Avtex Fibers Inc. Changes were suggested by Avtex Fibers to the proposed dates governing completion of interim control equipment on Boiler Numbers one (1) and two (2) and the date for entering into contracts for continuous particulate matter removal equipment necessary for final compliance. The EPA agrees that these changes are reasonable and will not affect the Company's overall ability to comply with the order in the most expeditious manner. Therefore, the dates of April 30, 1978 for completion of interim control equipment on Boiler Number one (1), June 30, 1978 for completion of interim control equipment on Boiler Number two (2), and April 30, 1978 for entering into contracts for particulate matter removal equipment, have been changed to

August 15, 1978, September 30, 1978, and May 31, 1978, respectively.

Secondly, the Avtex Fibers noted that the proposed primary standard condition of 218 pounds of particulate matter per hour for Boiler Numbers one (1), two (2), and three (3), and that of 275 pounds of particulate matter per hour for Boiler Numbers four (4) and five (5), are the emission levels that constitute best practicable interim control which will not cause or contribute significantly to a violation of the particulate matter standard under annual operating conditions. Since the Company would be unable to maintain the above levels on a day-to-day basis, a further demonstration was required to determine the maximum hourly allowable emission limitations which would not cause or contribute to a violation of the 24 hour standard for particulate matter. These levels were identified as 262 pounds of particulate matter for Boiler Numbers one (1), two (2), and three (3), and 330 pounds of particulate matter for Boiler Numbers four (4) and five (5). The EPA recognizes in the case of Avtex Fibers, that control of allowable emissions to guard against a violation of the 24 hour standard also provides reasonable assuredness that the Company will not cause or contribute to a violation of the annual standard. Therefore, the proposed primary standard condition of 218 pounds of particulate matter per hour for Boiler Numbers one (1), two (2), and three (3), and 275 pounds of particulate matter per hour for Boiler Numbers four (4) and five (5), have been changed to 262 and 330 pounds of particulate matter per hour, respectively.

Lastly, the EPA proposed order required that the Company install a continuous opacity monitor for each stack serving Boiler Numbers one (1), two (2), and three (3). The Company indicated that the control equipment to be installed will be a single structure to accommodate all five (5) boilers and that it will be discharging to a single stack. The five (5) existing boiler stacks will be dismantled upon completion of the control equipment installation. The Company further indicated that they will install a permanent opacity monitor in the single new stack following installation and operation of the control equipment. As a result, EPA is deleting the requirement for installation of opacity monitors and in its place is requiring that the Company conduct and record visible emissions observations on the exhaust gas emissions by means of certified observers. Such observations shall be conducted in accordance with EPA Method nine (9) as specified in Appendix A of Part 60, Title 40 of the Code of Federal Regulations, as amended.

As indicated in the proposed notice of May 15, 1978, regulations promulgated in 40 CFR Part 55 under the authority of Section 119 of the Act, as in effect prior to the amendments of August 1977, are being revised to reflect this statutory change. Any extensions to be granted under the new authority of 113(d)(5) will be promulgated in Part 55. Because of the shorter time period necessary for promulgation of a delayed compliance order (DCO) as compared to the time necessary for revision of the regulations under 40 CFR Part 55, this order for Avtex Fibers Inc. is promulgated under Part 55 prior to the publication of the revised regulations.

One major change that the Clean Air Act Amendments of 1977 have had on implementation of the Energy Supply and Environmental Coordination Act is that written concurrence of the Governor of the appropriate State must be obtained on any date EPA proposes to certify to the Department of Energy as the earliest date a prohibited source can convert to coal in compliance with applicable air pollution requirements. See Pub. L. 95-95, Section 112(b)(1). This concurrence was requested of the Honorable John N. Dalton, Governor of the Commonwealth of Virginia, and was received on July 5, 1978.

Therefore, based upon the request by Avtex Fibers, the rebuttal of regional limitation, the EPA's findings, and the written concurrence from Governor John N. Dalton, this order is hereby issued. In addition, this order is being made effective immediately since no purpose would be served by delaying its effective date.

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

Dated: December 14, 1978.

DOUGLAS M. COSTLE,
Administrator.

Part 55 of Chapter I, Title 40 of the Code of Federal Regulations is amended by adding a new section to Subpart VV as follows:

SUBPART VV—VIRGINIA

§ 55.971 Delayed Compliance Order.

The Administrator hereby issues a delayed compliance order to Avtex Fibers Inc., Front Royal Plant, Boiler Numbers one (1), two (2), and three (3), Front Royal, Virginia ("the source"), upon the following conditions:

(a) *Primary standard conditions.* The source shall not burn coal which results in the emissions of particulate matter in excess of 262 pounds of particulate matter per hour from either Boiler Numbers one (1), two (2), or three (3) and 330 pounds of particulate matter per hour from either Boiler Numbers four (4) or five (5) in

accordance with the following schedule of compliance:

(1) During the period of the order's effectiveness, Avtex Fibers shall operate and maintain the particulate collection equipment on Boiler Numbers one (1), two (2), and three (3) to ensure a minimum removal efficiency of 86 percent at total capacity, and on Boiler Numbers four (4) and five (5) a minimum removal efficiency of 82 percent at total capacity.

(2) During the period of the order's effectiveness, Avtex Fibers shall not burn coal with an ash content exceeding 10 percent and a heating value of less than 12,500 BTU's per pound.

(3) Within 30 days of the effectiveness of this order, Avtex Fibers shall submit a proposal for a complete air quality monitoring network to be set up by the source as required by subparagraph (VI)(A)(1).

(4) Within 90 days after receiving EPA approval of the proposed network, Avtex Fibers shall complete installation and begin operation of the air quality monitoring network.

(5) Within 90 days of the effectiveness of this order, Avtex Fibers shall submit for EPA approval the methods, procedures, and devices the Company intends to use to obtain the information required by subparagraph (VI)(B).

(b) *Plan for compliance with Section IV, Rules 2 and 3.* The source shall comply with Section IV, Rule 2 (effective date: March 17, 1972) and Rule 3 (effective date: March 17, 1972; amended August 11, 1972) of the Commonwealth of Virginia in accordance with the following increments of compliance:

(1) Completed—Complete on-site construction of high efficiency multicyclone collector on Boiler Number three (3).

(2) August 15, 1978—Complete on-site construction of high efficiency multicyclone collector on Boiler Number one (1).

(3) September 30, 1978—Complete on-site construction of high efficiency multicyclone collector on Boiler Number two (2).

(4) Completed—Enter into contracts for particulate emissions controls and other equipment necessary for final compliance.

(5) June 30, 1978—Submit for approval to the Director of the EPA, Region III, Air and Hazardous Materials Division (hereinafter referred to as "the Director"), contracts for continuous particulate emissions reduction systems and other equipment necessary for final compliance.

(6) April 30, 1979—Initiate on-site construction or installation of continuous particulate control systems.

(7) April 30, 1980—Complete on-site construction or installation of continuous particulate control systems.

(8) June 30, 1980—Perform emissions tests in accordance with 40 CFR Part 60 and submit reports demonstrating final compliance with the Regulations of the Commonwealth of Virginia, Section IV, Rules 2 and 3.

(c) *Interim requirements.* The source shall comply with the following interim requirements prior to achieving compliance with Section IV, Rules 2 and 3 of the Commonwealth of Virginia.

(1) Within 60 days of commencing the use of coal in Boiler Number two (2), Avtex Fibers shall perform source testing for particulate emissions using EPA Method Five (5) as specified in Appendix A of Part 60, Title 40 of the Code of Federal Regulations, as amended. The Company shall perform such tests in a manner prescribed by EPA Region III and shall provide the Regional Energy Coordinator a minimum of 15 days written notice prior to conducting such tests. The Avtex Fibers Inc. shall provide a complete report containing all information pertinent to the performance and results of the stack tests within 30 days of completing such tests.

(2) Within 120 days of the effectiveness of this order, Avtex Fibers shall conduct and record visible emissions observations on the exhaust gas emissions from Boiler Numbers one (1), two (2), and three (3). Such observations shall be conducted by certified observers in accordance with EPA Method Nine (9) as specified in Appendix A of Part 60, Title 40 of the Code of Federal Regulations, as amended. Such observations shall be for a period of at least one continuous hour per stack per day.

(3) The Avtex Fibers shall keep monthly records of air quality and air pollution emissions data and shall be submitted within 15 days of the end of each calendar month. These records shall detail daily emissions for all fuel-burning units and shall include:

(i) Fuel consumption for each day of the preceding month.

(ii) Analysis of the fuel consumed during each week to include sulfur content, ash content and high heating value.

(iii) For the stacks serving Boiler Numbers one (1), two (2), and three (3), a record of the hourly visible emissions observations on the exhaust gas emissions by means of certified observers.

(4) The Avtex Fibers Inc. shall notify the Director of any instances of exceeding the National Primary Ambient Air Quality Standards within 72 hours of the collection of such data.

(5) The Avtex Fibers Inc. shall notify the Director within 10 days

after each incremental requirement has been satisfied, or within 10 days after the final date set for achieving each such requirement, if such requirement has not been achieved.

(d) Violation of any requirement of this order shall result in one or more of the following actions:

(1) Enforcement of such requirement pursuant to subsection 113 (a), (b), or (c) of the Clean Air Act, including possible judicial action for injunction and/or penalties and in appropriate cases, criminal prosecution.

(2) Revocation of this order, after notice and opportunity for a public hearing, and subsequent enforcement of the Virginia State Implementation Plan.

(3) If such violation occurs on or after July 1, 1979, notice of noncompliance and subsequent action pursuant to Section 120 of the Act.

(e) Nothing herein shall affect the responsibility of Avtex Fibers Inc. to comply with State, local, or other Federal laws or regulations.

The entire order is hereby referenced. Any terms or conditions appearing in the order and not contained herein does not excuse compliance by Avtex Fibers Inc.

[FR Doc.78-35512 Filed 12-21-78; 8:45 am]

[6560-01-M]

[FRL 1010-2]

PART 65—DELAYED COMPLIANCE ORDERS

Delayed Compliance Order for the Naval Training Center, Orlando, Florida

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Administrator of EPA hereby issues a Delayed Compliance Order (DCO) to the Naval Training Center (NTC). The DCO requires the NTC to bring air emissions from its pathological waste incinerator into compliance with certain regulations contained in the federally-approved Florida State Implementation Plan (SIP). The Naval Training Center's compliance with the DCO will preclude suits under the federal enforcement and citizen suit provisions of the Clean Air Act for violation(s) of the SIP regulations covered by the DCO during the period the DCO is in effect.

DATES: This rule takes effect on December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Wayne Aronson, Air Enforcement Branch, Enforcement Division, EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308, telephone number: 404/881-4253.

ADDRESSES: The Delayed Compliance Order, supporting material, and any comments received in response to a prior FEDERAL REGISTER notice proposing issuance of the DCO are available for public inspection and copying during normal business hours at: Air Enforcement Branch (3rd Floor), EPA, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308.

SUPPLEMENTARY INFORMATION: On August 10, 1978, the Regional Administrator of EPA's Region IV Office published in the FEDERAL REGISTER, (43 FR 35508), a notice setting out the provisions of a proposed Delayed Compliance Order for the NTC's pathological waste and classified material incinerator. The notice asked for public comments and offered the opportunity to request a public hearing on the proposed DCO. No comments or requests for a public hearing were received

during the 30-day period provided in the informal proposed rulemaking procedure.

Subsequent to the August 10, 1978, FEDERAL REGISTER publication of the proposed Delayed Compliance Order for the Naval Training Center, the classified material incinerator located in Orlando, Florida, achieved compliance with the Florida State Implementation Plan. The classified material incinerator is no longer in violation of the Florida SIP provisions covered by the proposed DCO.

Dated: December 14, 1978.

DOUGLAS M. COSTLE,
Administrator.

In consideration of the foregoing, Chapter 1 of Title 40 of the Code of Federal Regulations is amended as follows:

1. By amending the table in § 65.140 by adding an entry to read as follows:

§ 65.140 Federal Delayed Compliance Orders issued under Section 113(d) (1), (3), and (4) of the Act.

* * * * *

Source	Location	Docket No.	Date of FR Proposal	SIP Regulation Involved	Final Compliance Date
Naval Training Center (pathological waste incinerator).	Orlando, Florida.	DCO-78-3	8/10/78 (43 FR 35508).	Chapter 17-2.04(6)(a)2a.	1/15/79

[FR Doc. 78-35528 Filed 12-21-78; 8:45 am]

[4310-10-M]

Title 41—Public Contracts and Property Management

CHAPTER 14—DEPARTMENT OF THE INTERIOR

PART 14-19—TRANSPORTATION

Ocean Transportation on Privately Owned United States Flag Vessels; Correction

AGENCY: Interior Department.

ACTION: Correction to final rule.

SUMMARY: This document makes certain corrections to FR Doc. 78-31336, appearing at page 51635 in the Monday, November 6, 1978 issue of the FEDERAL REGISTER concerning ocean transportation on privately owned vessels of commodities contracted for that require ocean transportation. This correction adds the effective date which was inadvertently omitted and a few other editorial changes are made.

Part 14-19 is corrected as set forth below.

FOR FURTHER INFORMATION CONTACT:

William Opdyke, 202-343-5914.

CORRECTIONS

In FR Doc. 78-31336, appearing at page 51635 in the issue of Monday, November 6, 1978, the following corrections are made:

1. Add the following:

EFFECTIVE DATE: This amendment is effective December 6, 1978.

2. The Table of Contents is amended by adding the following entry preceding § 14-19.108-50:

Subpart 14-19.1—General

Sec.
14-19.108 Ocean transportation

* * * * *

3. A section caption is added to the basic regulations and preceding § 14-19.108-50 as follows:

Subpart 14-19.1—General

§ 14-19.108 Ocean transportation.

* * * * *

Dated: December 11, 1978.

RICHARD R. HITE,
Deputy Assistant
Secretary of the Interior.

[FR Doc. 78-35665 Filed 12-21-78; 8:45 am]

[4310-10-M]

PART 14-55—PROCUREMENT OF SERVICES

Contracts for Consulting Services and Management Studies and Services

AGENCY: Department of the Interior.

ACTION: Final rule.

SUMMARY: This rule makes changes to the Interior Procurement Regulations concerning contracts for management studies and services. The amendment implements the requirements of OMB Bulletin No. 78-11 concerning guidelines for the use of consulting services.

EFFECTIVE DATE: January 22, 1979.

FOR FURTHER INFORMATION CONTACT:

William Opdyke, 202-343-5914.

SUPPLEMENTARY INFORMATION:

BACKGROUND

The regulations contained in 41 CFR Subpart 14-55.2 prescribe policy and procedures for procurement of management studies and services. The regulations require Departmental approval for contracts exceeding \$10,000 for management assistance or consulting services ranging from specific advice and guidance to comprehensive analysis, surveys or studies dealing with a broad range of administrative, management and program activities.

Guidelines for the use of consulting services were issued on May 5, 1978, by the Office of Federal Procurement Policy, Office of Management and Budget under OMB Bulletin No. 78-11.

This rule implements the requirements of OMB Bulletin No. 78-11 by amending 41 CFR Subpart 14-55.2. The principal changes include:

1. A revised statement of policy;
2. Approval by the Director, Office of Administrative and Management

Policy, of covered contracts which exceed \$10,000;

3. Specific inclusion of consulting services;

4. Additional examples of the types of studies and services that require Departmental approval;

5. A definition of consulting services; and

6. A requirement concerning conflict of interest.

Changes have been made throughout the Subpart which necessitates a complete revision.

PRIMARY AUTHOR

The primary author of this rule is William Opdyke, Division of Procurement and Grants, Office of Administrative and Management Policy, Department of the Interior, 18th and C Streets, N.W., Washington, D.C. 20240, telephone 202-343-5914.

WAIVER

It is the general policy of the Department of the Interior to allow time for interested parties to participate in the rulemaking process. However, the amendments contained herein are entirely administrative in nature and public participation would be inappropriate. Therefore, the public rulemaking process is waived in this instance in accordance with 5 U.S.C. 553.

IMPACT

The Department of the Interior has determined that this document does not contain a major rule requiring preparation of an Inflation Impact Statement under Executive Order 11821 or OMB Circular A-107.

Accordingly, pursuant to the authority of the Secretary of the Interior contained in 5 U.S.C. 301, 41 CFR Chapter 14 is amended as stated below.

Dated: December 11, 1978.

RICHARD R. HITE,
Deputy Assistant Secretary
of the Interior.

Subpart 14-55.2—Contracts for Consulting Services and Management Studies and Services

1. The table of contents for Part 14-55 is amended by revising the entries for Subpart 14-55.2 to read as follows:

* * *

Subpart 14-55.2—Contracts for Consulting Services and Management Studies and Services

Sec.	
14-55.200	Scope of subpart.
14-55.201	Policy.
14-55.202	Applicability.
14-55.203	Definitions.
14-55.204	Procedures.

* * *

2. Subpart 14-55.2 is revised to read as follows:

Subpart 14-55.2—Contracts for Consulting Services and Management Studies and Services

§ 14-55.200 Scope of subpart.

This subpart prescribes policies and procedures relative to procurement of consulting services and management studies and services by contract.

§ 14-55.201 Policy.

It is the policy of the Department of the Interior to ensure that consulting services and management studies and services are appropriate and necessary and that the requirements and end products for these procurements are clearly defined. All requirements and any justifications for noncompetitive procurement shall be reviewed and approved by the Director, Office of Administrative and Management Policy, before any procurement action is taken.

§ 14-55.202 Applicability.

(a) The policy and procedures of this subpart apply to all procuring activities of the Department for contracts exceeding (or expected to exceed) \$10,000 for management assistance or consulting services ranging from specific advice and guidance to comprehensive analysis, surveys or studies dealing with, but not limited to:

(1) Policy and program planning, analysis and development; e.g., policy development, program planning, economic analysis and program impact;

(2) Program review and evaluation;

(3) Organization or management planning, review or analysis; e.g., management or operational reviews, management audits and reviews and surveys of operations;

(4) Systems requirements, feasibility studies and system development; e.g., management information systems, accounting systems, personnel management systems and planning;

(5) Employee development and training programs; e.g., development of curriculum or instructional materials, instructor's guides and training handbooks;

(6) Methods and procedures and efficiency or productivity studies of systems; e.g., operations research studies, paperwork management, management services work and model development; and

(7) Energy management studies and services; e.g., on-site building surveys to identify reduction in both energy cost and operating cost; analysis of existing motor vehicle preventive main-

tenance programs; training programs; and energy program promotion.

(b) Excluded from these provisions are the following:

(1) Personal services of experts and consultants covered by the authority of 5 U.S.C. 3109;

(2) Contracts for services covered by Subpart 14-55.1 of this chapter (including university research contracts; architectural and engineering services; scientific research, development and testing; and manufacturing and technical services unrelated to the services listed in paragraph (a) of this § 14-55.202).

(3) Contracts for systems requirements and feasibility studies for strictly technical or scientific systems; and

(4) Contracts which are included under the provisions of Part 306 of the Departmental Manual (306 DM 4) concerning automatic data processing procurement.

§ 14-55.203 Definitions.

(a) "Solicitations for contracted management studies and services and consultant services" means all solicitations, formal or informal, for management studies or services and consultant services as specified in § 14-55.202(a) to be accomplished under a contract or purchase order, including letter requests and requests for proposals.

(b) "Management study or service and consultant service contract" means any contract for services as specified in § 14-55.202(a), including basic ordering agreements and their task orders, indefinite delivery contracts and their task orders and any contract modification which extends or renews the contract or significantly changes the scope of work or increases the total contract price by more than \$10,000.

(c) "Consulting services" means those services of a purely advisory nature relating to the governmental functions of agency administration and management and agency program management.

§ 14-55.204 Procedures.

(a) Procuring activities shall observe the requirements of Part 365 of the Departmental Manual (365 DM 1) concerning responsibilities, advance review and approval, selection panel, contract monitoring and notification of completion applicable to contracts for management studies and services and consulting services.

(b) Upon approval of a request to contract for a management study or service or consulting service, the procuring activity will prepare the solicitation which shall include, in addition to other applicable requirements, the following:

(1) A statement that the award may be made without further discussion of proposals so that the proposal should be submitted initially on the most favorable terms as provided under § 1-3.805-1(a) of this title;

(2) A requirement that the offerors will submit a separate business or cost proposal and a separate proposal regarding technical considerations, qualifications and key personnel;

(3) A statement that offerors shall state on proposals any restrictions against disclosure of information for purposes other than proposal evaluation;

(4) A complete statement of the work and adequate information so that offerors have a clear understanding of the background and dimensions of the requirement;

(5) The objectives and scope of the project shall be clearly defined, with limitations, if any, on the contractor;

(6) A requirement that the offeror will specify in the proposal the approach that will be used to accomplish the statement of work;

(7) The evaluation criteria, listed in the order of descending importance, which will be used to evaluate the proposals;

(8) A clear statement of the items to be delivered and the period of performance; and

(9) A provision warning offerors concerning conflict of interest and a requirement for appropriate disclosure by offerors of any conflict of interest.

[FR Doc. 78-35541 Filed 12-21-78; 8:45 am]

[1505-01-M]

Title 45—Public Welfare

CHAPTER X—COMMUNITY SERVICES ADMINISTRATION

[CSA Instruction 6903-1a]

PART 1069—GRANTEE PERSONNEL MANAGEMENT

Subpart—Policy and Procedures on \$18,000 Per Year Salary Limitation

Correction

In FR Doc. 78-34421 appearing at page 57890 in the issue for Monday, December 11, 1978, the EFFECTIVE DATE should read "January 10, 1979."

[7035-01-M]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER D—TARIFFS AND SCHEDULES

[Docket No. 37086]

PART 1330—FILING QUOTATIONS FOR GOVERNMENT SHIPMENTS AT REDUCED RATES

Require One Copy of Government Shipment Quotations Instead of Two

AGENCY: Interstate Commerce Commission.

ACTION: Final rule.

SUMMARY: Former section 22 of the Interstate Commerce Act (49 U.S.C. 10721) authorizes the transportation of government traffic at reduced rates under certain circumstances. The Commission now requires that the rate quotations or tenders be in writing and that two copies be filed. However, only one copy is actually needed. Therefore, this document amends 49 CFR 1330.5 to require the filing of only one copy. Certain other minor modifications in the existing rule are also being made. A rulemaking proceeding pursuant to section 553 of the Administrative Procedure Act is unnecessary because this change is designed to lessen a burden on members of the public and will not result in any adverse effect on any person.

EFFECTIVE DATE: February 1, 1979.

ADDRESS: Section of Tariffs, Bureau of Traffic, Room 4333 Interstate Commerce Commission, Washington, D.C. 20423.

FOR FURTHER INFORMATION CONTACT:

William P. Geisenkotter, Chief, Section of Tariffs, Bureau of Traffic, Interstate Commerce Commission, Washington, D.C. 20423 (202-275-7739).

This decision does not significantly affect the quality of the human environment.

It is ordered:

1. Part 1330 of Title 49 of the Code of Federal Regulations is amended by revising § 1330.1 and § 1330.5 as follows:

§ 1330.1 Applicability.

The provisions of this part shall apply to copies of quotations or tenders made by all common carriers by railroad, including express and sleeping-cars companies, by pipeline, by motor vehicle, and by water, and freight forwarders, to the United

States Government, or any agency or department thereof, for the transportation, storage or handling of property or the transportation of persons free or at reduced rates as permitted by 49 U.S.C. 10721, except quotations or tenders which, as indicated by the United States Government or any department or agency thereof to any carrier or carriers, involves information the disclosure of which would endanger the national security.

§ 1330.5 Manner of submitting quotations.

(a) *General.* Copies of all quotations or tenders by common carriers to which this part applies, concerning rates, fares, or charges for the transportation, storage, or handling of property, or the transportation of persons free or at reduced rates, including quotations or tenders for retroactive application whether negotiated or renegotiated after the services have been performed, which are submitted to the Interstate Commerce Commission on and after the effective date of this part in conformity with the provisions of paragraph (b)(2) of 49 U.S.C. 10721 shall conform to this section.

(b) *Copy to be submitted concurrently with submittal to government agencies.* One exact copy of the quotation or tender shall be submitted to the Commission concurrently with the submittal of the quotation or tender to the Federal department or agency for whose account the quotation or tender is offered or the proposed services are to be rendered. The copy will be maintained at the Washington office of this Commission. It shall be signed and shall clearly indicate the name and official title of the officer executing the document. The copy filed with the Commission shall be numbered consecutively in a series maintained by the carrier or agent beginning with "1".

(c) *Filing procedure.* The copy shall be filed with a letter of transmittal which shall clearly indicate that it is being filed in accordance with the requirements of Section 10721. It must be addressed to the "Interstate Commerce Commission, Washington, D.C. 20423", with the envelope marked as containing "Government Shipment Quotation", and delivered free of all charges. If receipt for the document is desired, the letter of transmittal must be sent in duplicate, and one copy showing date of receipt by the Commission will be returned to the sender.

(d) *Quotation or tender superseding prior one.* A quotation or tender which supersedes a prior quotation or tender shall cancel, by a statement shown immediately under the number of the new document, the prior document by number.

2. This decision and the amended regulations shall become effective February 1, 1979.

3. Notice of this decision will be given to the public by depositing a copy in the office of the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, for public inspection, and by delivering a copy to the Director, Office of the Federal Register, for publication in the FEDERAL REGISTER as notice to all interested persons.

This decision is issued under authority of 49 U.S.C. 10321 and 10721.

Decided: December 13, 1978.

By the Commission, Chairman O'Neal, Vice Chairman Christian, Commissioners Brown, Stafford, Gresham, and Clapp.

Nancy L. Wilson,
Acting Secretary.

[FR Doc. 78-35580 Filed 12-21-78; 8:45 am]

[4310-55-M]

Title 50—Wildlife and Fisheries

CHAPTER 1—UNITED STATES FISH AND WILDLIFE SERVICE, DEPARTMENT OF THE INTERIOR

PART 33—SPORT FISHING

Opening of Pocasse National Wildlife Refuge, South Dakota, to Sport Fishing

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special Regulation.

SUMMARY: The Director has determined that the opening to sport fishing of Pocasse 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: Effective January 1, 1979 through December 31, 1979.

FOR FURTHER INFORMATION CONTACT:

Refuge Manager, Sand Lake NWR, Columbia, SD 57433 (605) 885-6320.

SUPPLEMENTARY INFORMATION:

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas

Sport fishing is permitted on Pocasse National Wildlife Refuge, South Dakota, only on the areas designated by signs as being open to fishing. These areas comprising 600 acres are delineated on maps available at the refuge headquarters and from the office of the Regional Director, U.S. Fish and Wildlife Service, PO Box

25486, Denver Federal Center, Denver, Colorado 80225. Sport fishing shall be in accordance with all State Regulations, subject to the following condition:

1. The use of boats is permitted northwest of Highway 10 only; boats are not permitted southeast of Highway 10.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas which are set forth in Title 50 Code of Federal Regulations, Part 33.

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.

(Sec. 2, 33 Stat. 614, as amended, sec. 5, 43 Stat. 651, secs. 5, 10, 45 Stat. 449, 1224, secs. 4, 2, 48 Stat. 402, as amended, 451, 1270, sec. 4, 76 Stat. 654; 5 U.S.C. 301, 16 U.S.C. 685, 725, 690d, 715i, 664, 718d, 43 U.S.C. 315a, 16 U.S.C. 460k; sec. 2, 80 Stat. 926; 16 U.S.C. 668bb.)

Dated: December 13, 1978.

SAM WALDSTEIN,
Refuge Manager.

[FR Doc. 78-35558 Filed 12-21-78; 8:45 am]

[4310-55-M]

PART 33—SPORT FISHING

Opening of Sand Lake National Wildlife Refuge, S. Dak., to Sport Fishing

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Special Regulation.

SUMMARY: The Director has determined that the opening to sport fishing of Sand Lake 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: January 1, 1979 through December 31, 1979.

FOR FURTHER INFORMATION CONTACT:

Refuge Manager, Sand Lake NWR, Columbia, SD 57433 (605) 885-6320.

SUPPLEMENTARY INFORMATION:

§ 33.5 Special regulations; sport fishing; for individual wildlife refuge areas

Sport fishing is permitted on the Sand Lake National Wildlife Refuge, South Dakota, only on the areas designated by signs as being open to fishing. These areas comprising 150 acres are delineated on maps available at the refuge headquarters and from the office of the Regional Director, U.S.

Fish and Wildlife Service, P.O. Box 25486, Denver Federal Center, Denver, Colorado 80225. Sport fishing shall be in accordance with all applicable State regulations subject to the following conditions:

1. The use of boats is not permitted.

The provisions of this special regulation supplement the regulations which govern fishing on wildlife refuge areas generally which are set forth in Title 50 Code of Federal Regulations, Part 33. 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.

(Sec. 2, 33 Stat. 614, as amended, sec. 5, 43 Stat. 651, secs. 5, 10, 45 Stat. 449, 1224, secs. 4, 2, 48 Stat. 402, as amended, 451, 1270, sec. 4, 76 Stat. 654; 5 U.S.C. 301, 16 U.S.C. 685, 725, 690d, 715i, 664, 718d, 43 U.S.C. 315a, 16 U.S.C. 460k; sec. 2, 80 Stat. 926; 16 U.S.C. 668bb.)

Dated: December 13, 1978.

SAM WALDSTEIN,
Refuge Manager.

[FR Doc. 78-35559 Filed 12-21-78; 8:45 am]

[3510-22-M]

CHAPTER VI—FISHERY CONSERVATION AND MANAGEMENT, NATIONAL OCEANIC AND ATMOSPHERIC ADMINISTRATION, DEPARTMENT OF COMMERCE

PART 611—FOREIGN FISHING

Increase of Foreign Allocations Regulations

AGENCY: National Oceanic and Atmospheric Administration/Commerce.

ACTION: Amendment to preliminary management plan to increase the total allowable level of foreign fishing (TALFF) in foreign fishing regulations for Atlantic squid.

SUMMARY: On November 29, 1978, proposed amendments to the preliminary management plan (PMP) for the squid fisheries of the Northwestern Atlantic were published in the FEDERAL REGISTER (43 FR 55809). That proposal reduced the U.S. harvesting capacity estimates of long-finned squid by 1,900 mt and estimates increased the TALFF by a corresponding 1,900 mt. No comments were received on these proposed amendments. Consequently the PMP is amended as proposed, and corresponding changes are made to the 1978 foreign fishing regulations.

EFFECTIVE DATE: December 19, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. William G. Gordon, Director, Northeast Regional Office, National Marine Fisheries Service, 14 Elm Street, Federal Building, Gloucester, Massachusetts 01930, Telephone: (617) 281-3600.

SUPPLEMENTARY INFORMATION: The foreign fishing regulations for 1978 which appeared at 42 FR 60682, on November 28, 1977, initially established the total allowable level of foreign fishing (TALFF) for long-finned squid at 19,000 mt. However, the 1978 foreign fishing regulations (§ 611.20) stated that " * * * as soon as possible" after June 15 the U.S. harvesting capacity would be reassessed, "based on updated information relating to status of stocks, estimated and actual performance of domestic and foreign fleets in current and prior years, and other relevant factors."

The National Marine Fisheries Service has surveyed all known active processors of squid in the Northeastern United States concerning their desired 1978 squid pack and has determined that the original estimate of U.S. harvesting capacity in 1978 for long-finned (*Loligo*) squid was too high. The Assistant Administrator has determined, therefore, that the estimated 1978 U.S. harvesting capacity for

long-finned squid should be reduced by 1,900 mt (from 25,000 mt to 23,100 mt). The Assistant Administrator has also determined that the 1,900 mt surplus of long-finned squid should be added to the TALFF, increasing it from 19,000 mt to 20,900 mt.

The Assistant Administrator for Fisheries, under an appropriate delegation of authority, for good cause finds:

(1) That failure to make surplus resources available to foreign nations within a reasonable time is not consistent with the purpose and intent of the Fishery Conservation and Management Act of 1976;

(2) That these changes do not require the preparation of an environmental assessment; and

(3) That these changes do not require the preparation of regulatory impact analysis.

The PMP is revised as follows:

* * * * *

c. Estimated Domestic Production Potential and Allowable Foreign Surplus. The capacity of the United States to exploit squid in 1978 was estimated by the National Oceanic and Atmospheric Administration, in consultation with members of the U.S. fishing industry, as 29,100 mt. Of this amount, 23,100 mt was of long-finned squid (*Loligo*), and 6,000 mt was of short-finned squid (*Illex*). This left 49,900 mt of both species as foreign surplus. Specific figures by species are given in Table 26.

TABLE 26—Squid Optimum Yield and Allocations

[In metric tons]

Species	Maximum sustainable yield	Optimum yield	U.S. capacity	Foreign surplus
<i>Illex</i>	40,000	35,000	6,000	29,000
<i>Loligo</i>	44,000	44,000	23,100	20,900

Signed in Washington, D.C., this 19th day of December, 1978.

JACK W. GEHRINGER,
Deputy Assistant Administrator for Fisheries,
National Marine Fisheries Service.

(16 U.S.C. 1801 *et seq.*)

§ 611.20 [Amended]

Amend 50 CFR 611.20(c) by revising Table 1 as follows:

Line 7 is revised to read:

"Species Code"	"Species"	"Ocean Area"	"Amended TALFF (mt)"
501.....	Squid, long-finned.....	do.....	20,900

[FR Doc. 78-35698 Filed 12-21-78; 8:45 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-M]

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation
Service

[7 CFR Part 724]

FIRE CURED (TYPE 21), FIRE CURED (TYPES 22-24), DARK AIR CURED (TYPES 35-36), VIRGINIA SUN CURED (TYPE 37), CIGAR BINDER (TYPES 51 & 52), AND CIGAR FILLER & BINDER (TYPES 42-44; 53-55)

Proposed Determinations of Marketing Quotas for the 1979-80, 1980-81 and 1981-82 Marketing Years for Fire Cured (Type 21), Fire-Cured (Types 22-24), Dark Air Cured (Types 35-36) Virginia Sun Cured (Type 37), Cigar Binder (Types 51 & 52), and Cigar Filler and Binder (Types 42-44; 53-55) Tobaccos

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture is preparing to determine and announce national marketing quotas for the minor kinds of tobacco for the 1979-1980 marketing year. The quotas must be announced by February 1, 1979. Interested persons are invited to submit written comments, views and recommendations concerning the proclamation and announcement of quotas, the referendum to be held, and other related matters.

DATES: Written comments must be received by January 15, 1979 in order to be sure of consideration.

ADDRESSES: Send comments to the 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 L. Tarczy, (202) 447-7601.

SUPPLEMENTARY INFORMATION: The Agricultural Adjustment Act of 1938, as amended (hereinafter referred to as the "Act"), requires the Secretary (1) with respect to fire-cured (type 21), fire cured (types 22-24) and dark air cured (types 35-36) tobaccos to proclaim national marketing quotas for the 1979-80, 1980-81, and 1981-82 marketing years and to conduct, within 30 days after proclamation of such national marketing quotas, refer-

endums of farmers engaged in the 1978 production of such respective kinds of tobacco to determine whether they favor or oppose marketing quotas for such years; and (2) with respect to fire-cured (type 21), fire-cured (types 22-24), dark air-cured, Virginia sun-cured, cigar binder (types 51 & 52), and cigar filler and binder (types 42-44 & 53-55) tobacco, to determine and announce the amounts of the national marketing quotas for each of such kinds of tobacco for the 1979-80 marketing year; to convert such marketing quotas into national acreage allotments and announce the allotments; to apportion such allotments, less reserves of not to exceed 1 per centum of each respectively, through the local ASCS county committees among old farms and to apportion the reserves for use in (a) establishing acreage allotments for new farms and (b) making corrections and adjusting inequities in old farm allotments.

Section 312(a) of the Act (7 U.S.C. 1312(a)) requires the Secretary to proclaim marketing quotas, not later than February 1, 1979, for fire-cured (type 21), fire-cured (types 22-24), and dark air-cured, (types 35-36) tobaccos for the three marketing years beginning October 1, 1979, because the 1978-79 marketing year is the last year of the three consecutive years for which marketing quotas previously proclaimed will be in effect for these kinds of tobacco.

Quotas were previously proclaimed, referendums conducted, and quotas approved by growers as follows: fire-cured and dark air-cured tobacco, for the 1976-77, 1977-78, and 1978-79 marketing years (41 FR 4881); Virginia sun-cured tobacco for the 1977-78, 1978-79 and 1979-80 marketing years (42 FR 6819); and cigar binder tobacco (types 51 & 52) and cigar-filler and binder tobacco (types 42-44 & 53-55) for the 1978-79, 1979-80, 1980-81 marketing years (43 FR 16410). Section 301(b)(15) of the Act (7 U.S.C. 1301(b)(15)) defines "tobacco" as each one of the kinds of tobacco listed below comprising the types specified as classified in Service and Regulatory Announcement Number 118 (Part 30 of this title) of the former Bureau of Agricultural Economics of the Department:

Flue-cured tobacco, comprising types 11, 12, 13, & 14;

Fire-cured tobacco, comprising type 21;

Fire-cured tobacco, comprising types 22, 23, & 24;

Dark air-cured tobacco, comprising types 35 & 36;

Virginia sun-cured tobacco, comprising type 37;

Burley tobacco, comprising type 31;

Maryland tobacco, comprising type 32;

Cigar filler and cigar binder tobacco, comprising types 42, 43, 44, 45, 46, 51, 52, 53, 54, & 55; and

Cigar filler tobacco, comprising type 41.

Section 301(b)(15) also provides that any one or more of the types comprising any such kind of tobacco shall be treated as a "kind of tobacco" for the purposes of the Act if the Secretary finds that there is a difference in supply and demand conditions as among such types of tobacco which results in a difference in the adjustments needed in the marketings thereof in order to maintain supplies in line with demand. Pursuant to this authority, the Secretary has determined (15 FR 8214) that type 46 tobacco shall be treated as a separate kind of tobacco for purposes of marketing quotas and price supports. Pursuant to such authority, the Secretary has also determined (22 FR 367) that cigar-binder (types 51 and 52) tobacco, beginning with the 1957-58 marketing year, shall be treated as a separate kind of tobacco for purposes of marketing quotas and price supports. Type 45 tobacco is no longer grown. No further action under this section is contemplated at this time.

Section 312(b) of the Act (7 U.S.C. 1312(b)) provides that the Secretary shall determine and announce, not later than the first day of February 1979 with respect to kinds other than flue-cured tobacco, the amount of the national marketing quota which will be in effect for the 1979-80 marketing year in terms of the total quantity of tobacco which may be marketed which will make available during such marketing year a supply of each kind of tobacco equal to the reserve supply level. Section 312(b) of the Act provides further that the amount of the 1979-80 national marketing quota so announced may, not later than March 1, 1979, be increased by not more than 20 per centum if the Secretary determines that such increase is necessary in order to meet market demands or to avoid undue restrictions of marketings in adjusting the total supply to the reserve supply level.

Section 301(b) of the Act (7 U.S.C. 1301(b)) defines the "total supply" of

PROPOSED RULE

any kind of tobacco (except type 46) for any marketing year as the carry-over at the beginning of the marketing year (or on January 1 of such marketing year in the case of Maryland tobacco) plus the estimated production in the United States during the calendar year in which such marketing begins. "Reserve supply level" is defined as the normal supply plus 5 per centum thereof. "Normal supply" is defined as a normal year's domestic consumption and exports, plus 175 per centum of a normal year's domestic consumption and 65 per centum of a normal year's exports. A "normal year's domestic consumption" is defined as the yearly average quantity produced in the United States and consumed in the United States during the 10 marketing years immediately preceding the marketing year in which such consumption is determined, adjusted for current trends in such consumption. A "normal year's" exports is defined as the yearly average quantity produced in the United States which was exported from the United States during the 10 marketing years immediately preceding the marketing year in which such exports are determined, adjusted for current trends in such exports.

Section 312(c) of the Act (7 U.S.C. 1312(c)) requires that within 30 days after a national marketing quota is proclaimed under §312(a) of the Act for a kind of tobacco, the Secretary shall conduct a referendum of farmers engaged in the production of the crop of such kinds of tobacco harvested immediately prior to the holding of the referendum to determine whether such farmers are in favor of or opposed to quotas for the next three succeeding marketing years. If more than one-third of the farmers voting in a referendum for a kind of tobacco oppose the quotas, such results shall be proclaimed by the Secretary and the national marketing quotas so proclaimed shall not be in effect, but such results shall in no way affect or limit the subsequent proclamation and submission to a referendum, as otherwise provided in §312, of a national marketing quota.

Section 313(g) of the Act (7 U.S.C. 1313(g)) authorizes the Secretary to convert the national marketing quota into a national acreage allotment on the basis of the national average yield for the five years immediately preceding the year in which the national marketing quota is proclaimed and to apportion the national acreage allotment (less a reserve of not to exceed 1 per centum thereof for new farms and for making corrections and adjusting inequities in old farm allotments) among old farms.

The Secretary is preparing to determine and announce for the 1978-79 marketing year for the minor kinds of tobacco:

1. The amount of the reserve supply level for fire-cured (type 21), fire-cured (types 22-24), dark air-cured, Virginia sun-cured, cigar binder (types 51 & 52) and cigar filler and binder (types 42-44 & 53-55) tobaccos.

2. The amount of the national marketing quota for each of these kinds of tobacco for the 1979-80 marketing year.

3. The national factors for apportioning national acreage allotments to old farms.

4. The amounts of the national acreage allotments to be reserved for new farms and for making corrections and adjusting inequities in old farm allotments.

5. The date(s) or period(s) of the referendums on quotas for the 1979-80, 1980-81, and 1981-82 marketing year for fire-cured (type 21), fire-cured (types 22-24), and dark air-cured (types 35 & 36) tobaccos, and whether the referendums should be conducted at polling places rather than by mail ballot (31 FR 12011).

Prior to making any determinations, the Secretary will give consideration to comments, views, and recommendations submitted in writing to the Director, Price Support and Loan Division. All written submissions made pursuant to the notice 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 quotas for the 1979-80 marketing year for other tobaccos is required by statute to be announced by February 1, 1979, 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 January 15, 1979 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 December 19, 1978.

STEWART N. SMITH,
Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 78-35712 Filed 12-21-78; 8:45 am]

[4110-07-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

[20 CFR Part 404]

[Regs. No. 4]

FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE

Requirements for Entitlement or Reentitlement
to Child's Benefits

AGENCY: Social Security Administration, HEW.

ACTION: Withdrawal of Notice of Proposed Rule Making.

SUMMARY: The Social Security Administration is withdrawing the proposed amendments to the regulations entitled "Requirements for Entitlement or Reentitlement to Child's Benefits," which was published in the FEDERAL REGISTER of April 1, 1977 (42 FR 17484).

EFFECTIVE DATE: This withdrawal will be effective December 22, 1978.

FOR FURTHER INFORMATION CONTACT:

Mrs. V. J. Schlosser, Legal Assistant,
Social Security Administration, 6401
Security Boulevard, Baltimore,
Maryland 21235, telephone (301)
594-7332.

SUPPLEMENTARY INFORMATION: After the publication of the Notice of Proposed Rule Making, the Secretary of Health, Education, and Welfare issued guidelines for writing regulations as part of Operation Common Sense. (See FEDERAL REGISTER of November 18, 1977, 42 FR 59555.) In light of the Secretary's initiatives, we have reviewed the Notice of Proposed Rule Making on "Requirements for Entitlement or Reentitlement to Child's Benefits," and have decided to address these policies in the recodification of Subpart D dealing with benefits. The Notice of Proposed Rule Making for this recodification was published on November 14, 1978; (43 FR 52936). Therefore, the proposed amendments published in the FEDERAL REGISTER of April 1, 1977 (42 FR 17484), entitled "Requirements for Entitlement and Reentitlement to Child's Benefits," are withdrawn.

Dated: November 8, 1978.

STANFORD G. ROSS,
Commissioner of Social Security.

Approved: December 12, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary of Health, Education,
and Welfare.

[FR Doc. 78-35636 Filed 12-21-78; 8:45 am]

[4210-01-M]

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Assistant Secretary for Housing—
Federal Housing Commissioner

[24 CFR Part 201]

[Docket No. R-78-593]

Increase in Loan Maturity for Double-Wide
Mobile Homes From 15 to 20 Years

Proposed Rule

AGENCY: Department of Housing
and Urban Development.

ACTION: Proposed Rule.

SUMMARY: The proposed amendment would increase the maturity period for an obligation financing the purchase of a mobile home consisting of two or more modules from 15 years and 32 days to 20 years and 32 days. The purpose of this rule is to implement Title III of the Housing and Community Development Act of 1977, Section 306(b). The Department of Housing and Urban Development, as a result of a recent study, has concluded that a mobile home consisting of two or more modules can attain 20 years of useful life provided that only one transportation trip occurs after manufacture, unless special specified shipping precautions are observed.

DATE: Interested persons are invited to submit written comments, data, suggestions or objections by January 22, 1979.

ADDRESS: All materials which persons wish to submit should be sent to the Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410. A copy of each comment will be available for public inspection at the above address during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Thomas C. Thornton, Acting Director, Title I Insured Loan Division, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, D.C. 20410 (202) 755-8686.

SUPPLEMENTARY INFORMATION: Section 306(b) of the Housing and Community Development Act of 1977

authorized a maturity period of 23 years and 32 days for an obligation financing the purchase of a mobile home composed of two or more modules. After careful review, it has been determined to increase the maximum maturity to 20 years and 32 days from the present maximum of 15 years and 32 days rather than the 23 year period authorized by the Act. If subsequent experience indicates that the maturity period should be increased to 23 years and 32 days, the regulations will be amended to effect the longer period.

The Department has determined that an environmental impact statement is not required with respect to this rule. A copy of the Finding of Inapplicability is available for inspection in the office of the Rules Docket Clerk, Room 521B, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, D.C. 20410.

Accordingly, § 201.560 is amended to read as follows:

§ 201.560 Maturity provision.

***, except that an obligation for a mobile home composed of two or more modules should have a term of not more than 20 years and 32 days. ***

(Sec. 7(d), Department of Housing and Urban Development Act, 79 sec. 670 (42 U.S.C. 3535(d) sec. 2, 48 Stat. 1248 (12 U.S.C. 1703).)

In accordance with Section 7(o)(4) of the Department of HUD Act, Section 324 of the Housing and Community Development Amendments of 1978, Pub. L. 95-557, 92 Stat. 2080, this proposed rule has been granted waiver of Congressional review requirements in order to permit publication at this time for public comment.

Issued at Washington, D.C., December 1, 1978.

LAWRENCE B. SIMONS,
Assistant Secretary for Housing,
Federal Housing Commissioner.

[FR Doc. 78-35693 Filed 12-21-78; 8:45 am]

[4830-01-M]

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[26 CFR Part 26]

[LR-2-77]

EFFECTIVE DATES OF GENERATION-SKIPPING TRANSFER TAX

Proposed Rulemaking

AGENCY: Internal Revenue Service,
Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to the

application of the effective date provisions of a new tax on generation-skipping transfers which was added by the Tax Reform Act of 1976.

The proposed regulations provide guidelines for determining whether an amendment to a will or trust will subject it to the provisions of the generation-skipping transfer tax.

DATES: Written comments and requests for a public hearing must be delivered or mailed by February 20, 1979.

ADDRESS: Send comments and requests for a public hearing to: Commissioner of Internal Revenue, Attention: CC:LR:T (LR-2-77), Washington, D.C. 20224.

FOR FURTHER INFORMATION CONTACT: Fred E. Grundeman of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224 (Attention CC:LR:T) (202-566-3295) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

BACKGROUND

This document contains proposed generation-skipping transfer tax regulations under Chapter 13 of the Internal Revenue Code of 1954, as added by section 2006 (a) of the Tax Reform Act of 1976 (the "Act") (Pub. L. 94-455; 90 Stat. 1879) and amended by section 702 (n) of the Revenue Act of 1978 (Pub. L. 95-600) to provide rules for applying the effective date to certain trusts. These regulations are to be issued under the authority contained in section 7805 of the Internal Revenue Code of 1954 (68A Stat. 917; 26 U.S.C. 7805).

IN GENERAL

A tax is imposed on every generation-skipping transfer. However, this tax is imposed only on generation-skipping transfers occurring after June 11, 1976. Also, certain trusts in existence on that date are excluded from the application of the generation-skipping transfer provisions. The Act further provides that a trust, which is otherwise excluded from the new tax, may become subject to the tax if additions to corpus are made after June 11, 1976. The proposed regulations provide rules for computing the generation-skipping transfer tax attributable to such additions to corpus.

The Act also provides that a will or trust which is initially excluded from the provisions of the Act may become subject to these provisions if the will or trust is amended in certain ways after June 11, 1976.

The proposed regulations provide guidelines for determining whether an amendment to a will or trust will sub-

ject it to the provisions of the generation-skipping transfer tax.

COMMENTS AND REQUESTS FOR A PUBLIC HEARING

Before adopting these proposed regulations, consideration will be given to any written comments that are submitted (preferably six copies) to the Commissioner of Internal Revenue. All comments will be available for public inspection and copying. A public hearing will be held upon written request to the Commissioner by any person who has submitted written comments. If a public hearing is held, notice of the time and place will be published in the FEDERAL REGISTER.

DRAFTING INFORMATION

The principal author of these proposed regulations was Fred E. Grundeman of the Legislation and Regulations Division of the Office of Chief Counsel, Internal Revenue Service. However, personnel from other offices of the Internal Revenue Service and Treasury Department participated in developing the regulation, both on matters of substance and style.

PROPOSED AMENDMENTS TO THE REGULATIONS

A new Part 26, Generation-Skipping Transfer Tax Regulations, is to be added to Title 26 of the Code of Federal Regulations, and the first regulations proposed to be contained in that part are as follows:

Part 26—Generation-Skipping Transfer Tax Regulations

Sec.
26.2601-1 Effective date.

AUTHORITY. Sec. 7805, Internal Revenue Code of 1954 (68A Stat. 917; (26 U.S.C. 7805).)

§ 26.2601-1 Effective Date.

(a) *In general.* Except as provided in paragraph (b) of this section, the provisions of Chapter 13 of the Code apply to any generation-skipping transfer, as defined in section 2611(a), made after June 11, 1976.

(b) *Exceptions.*—(1) *General rule.* The provisions of Chapter 13 of the Code will not apply to—

(i) Any generation-skipping transfer made pursuant to a trust (or trust equivalent within the meaning of section 2611(d)) which was irrevocable on June 11, 1976; or

(ii) Any generation-skipping transfer, in the case of a decedent dying before January 1, 1982, made pursuant to a will or revocable trust (or trust equivalent within the meaning of section 2611(d)) which was in existence on June 11, 1976, and was not amended at any time after that date in any respect which would result in the cre-

ation of a generation-skipping transfer or increase the amount of a generation-skipping transfer,

but in either case only to the extent the transfer is not made out of corpus added to the trust (or trust equivalent) after June 11, 1976. If a decedent on June 11, 1976, was under a mental disability to change the disposition of his property, or became so mentally disabled at any time before January 1, 1982, without having amended a dispositive provision or his will or trust after June 11, 1976, there will be substituted for "January 1, 1982" in the preceding sentence the date which is two years after the date on which the decedent first regains his competence to dispose of such property (if later than January 1, 1982).

(2) *Limited powers of appointment.* The preceding subparagraph does not apply to a trust (or trust equivalent) subject to a limited power of appointment if the power is exercised after June 11, 1976, so as to—

(i) Postpone the vesting of any estate or interest in the trust property, or

(ii) Suspend the absolute ownership or power of alienation of such property (where the applicable rule against perpetuities is stated in such terms)

for a period ascertainable without regard to the date of the creation of the trust. Such a power will be deemed to be so exercised if the power is exercised by creating another power and the second power can be validly exercised (or the applicable provisions in default of such exercise can operate) to postpone vesting or suspend ownership (as described in paragraph (b)(2)(i) or (ii) of this section) for a period ascertainable without regard to the date of the creation of the first power.

(c) *Revocable trusts.*—(1) *In general.* For purposes of this section, a trust in existence on June 11, 1976, is treated as a revocable trust to the extent that on that date it was subject to—

(i) A power to revoke or invade held by one or more persons;

(ii) A general power of appointment (as defined in sections 2041(b) or section 2514(c)) held by one or more persons; or

(iii) A power to change beneficiaries of any income or corpus of the trust (other than from one section 501(c)(3) organization to another section 501(c)(3) organization), if held by any person who transferred assets to the trust, whether or not that person can exercise the power with or without the consent of one or more persons.

(2) *Examples.* The provisions of paragraph (c)(1) of this section may be illustrated by the following examples:

Example (1). On June 11, 1976, Y, the spouse of the settlor of a marital deduction trust that was otherwise irrevocable on

June 11, 1976, had a life income interest and a general testamentary power of appointment over the trust. Because the trust is subject to a general power of appointment on June 11, 1976, it is treated as a revocable trust for purposes of this section. If Y dies before 1982 without exercising her testamentary power of appointment, the trust will not be subject to Chapter 13 if there is a generation-skipping transfer pursuant to the trust instrument after Y's death. However, if Y does not die before 1982, or if Y exercises the testamentary power of appointment in a manner that creates or increases a generation-skipping transfer, the entire trust will be subject to Chapter 13.

Example (2). On June 11, 1976, A, the wife of the settlor of a trust in existence on that date, had the right to withdraw \$5,000 in each calendar year from the trust. The trust was otherwise irrevocable on June 11, 1976. A does not exercise the power for any year after 1975, and she dies in 1983. Because the trust was subject to a power of invasion to the extent of \$5,000 a year, it is treated as revocable to that extent until A's death. Since A did not die before 1982, \$5,000 a year for each of the eight years after 1975 is considered an addition to corpus of a trust that was otherwise irrevocable on June 11, 1976. However, if A had died before 1982, \$5,000 (the portion of the trust that was revocable on June 11, 1976) would not be subject to Chapter 13 under paragraph (b)(1)(ii) of this section.

(d) *Additions to corpus.*—(1) *In general.* An addition made after June 11, 1976, to the corpus of a trust that was irrevocable on June 11, 1976, or to the corpus of a revocable trust in existence on June 11, 1976, will subject a proportionate amount of the transfers from such a trust to the provisions of Chapter 13 of the Code. In such a case, the portion subject to Chapter 13 is a fraction of the trust's total value. The numerator of this fraction is the amount of the addition (valued as of the date the addition was made), and the denominator is the total value of the trust immediately after the addition. Where there is more than one addition to corpus after June 11, 1976, the portion of the trust attributable to all such additions will be a similar fraction. The numerator of this fraction is the sum of:

(i) The total value of the trust which, immediately before the latest addition, is subject to Chapter 13, and

(ii) The amount of the latest addition.

The denominator of the fraction is the total value of the trust immediately after the latest addition.

(2) *Exceptions.* Any addition to a trust made pursuant to the will or revocable trust of a decedent dying before January 1, 1982, if such will or revocable trust meets the requirements of paragraph (b)(1)(ii) of this section will not be treated as an addition to corpus for purposes of paragraphs (b)(1) and (d)(1) of this section. In addition, any inter vivos transfer to a trust will not be treated as such an

addition to corpus if the same property or money would have been added to the trust by such a will or revocable trust (or passed in the same way) but for the inter vivos transfer. However, in any case where it cannot be determined at the time of the inter vivos transfer if the preceding sentence will apply, the inter vivos transfer will be deemed to be an addition to corpus until such time as a determination can be made.

(3) *Appreciation.* Appreciation in the value of assets held in a trust as of June 11, 1976, will not be considered an addition to corpus.

(4) *Income.* Undistributed income, not subject to a current power of withdrawal and accumulated in taxable years ending after December 31, 1978, will be considered an addition to the corpus of a trust in existence on June 11, 1976, for purposes of this paragraph (d). The term "undistributed income" means the excess of income (as determined under section 643(b)) over total amounts properly paid or credited or required to be distributed for the year to or for any current beneficiary of the trust. Any amount treated as a distribution for a prior year under section 663(b) will be considered as paid for the prior year for purposes of the preceding sentence. The term does not include income required to be accumulated under the terms of the governing instrument for any taxable year during which no discretionary power to distribute or demand trust assets exists.

(5) *Examples.* The provisions of this paragraph may be illustrated by the following examples:

Example (1). The settlor of a trust that was irrevocable on June 11, 1976, added \$6,000 to the trust corpus on July 30, 1976. Immediately following the addition, the corpus of the trust had a value of \$300,000. This addition represented 2 percent of the value of the corpus. The settlor had no will (or revocable trust) that was in existence on June 11, 1976. Distributions from the trust after the transfer on July 30, 1976, will be subject to the generation-skipping transfer provisions to the extent of 2 percent.

Example (2). On September 1, 1976, \$100,000 was added by the settlor to the corpus of a trust that was irrevocable on June 11, 1976, and that had a value of \$900,000 immediately before the addition. No other additions are made until February 1, 1981, when the corpus has a value of \$2,000,000. At that time a second addition of \$500,000 is made. The settlor has no will (or revocable trust) that was in existence on June 11, 1976. If a distribution is made from the trust between the transfer made on September 1, 1976, and the transfer made on February 1, 1981, 10% [that is, $\$100,000/(\$900,000 + \$100,000)$] of the distribution will be subject to the generation-skipping transfer provisions. To determine such a percentage after the February transfer, $\$200,000$ (10% of \$2,000,000, the value of the corpus immediately before the last addition) is treated as an amount that is added along with the \$500,000 added on that date.

Therefore, assuming that no other additions are made, 28% [that is, $\$200,000 + \$500,000/(\$2,000,000 + \$500,000)$] of any distribution made from the trust after February 1, 1981, will be subject to the generation-skipping transfer provisions.

Example (3). H is the grantor of an irrevocable generation-skipping trust which was in existence on June 11, 1976. H's will, which was executed before June 11, 1976, and not amended thereafter, provides that upon his death the entire estate will pour over into his trust. In 1980, H transfers \$10,000 to the trust. If H dies after 1981, the transfer will be treated as an addition to corpus for purposes of any distribution made after the transfer to the trust in 1980. If H dies before 1982, the entire trust (as well as any distribution made by the trust prior to his death) will be excluded under paragraphs (b)(1)(i) and (d)(2) of this section from the generation-skipping provisions, because the \$10,000 would have been added to the trust under a will which would have qualified under paragraph (b)(1)(ii) of this section. In either case, for any generation-skipping transfers made after the transfer to the trust in 1980 but before H's death (or before January 1, 1982, if earlier), the \$10,000 will be treated as an addition, to corpus and a proportionate amount of such transfer will be subject to the generation-skipping transfer provisions. If H dies before January 1, 1982, the person liable for any previously paid generation-skipping tax may file a claim for refund of such tax.

Example (4). W, the trustee of an irrevocable trust created by H that was in existence on June 11, 1976, and whose annual accounting period is the calendar year, had the discretionary power to distribute so much of the current net income as she felt desirable among a group consisting of A, B and C. She also had the duty to invade corpus for the support and maintenance of D, at D's request, without regard to D's income from any other source. During 1976 the trust had net income of \$10,000 that was not distributed and, from June 11, 1976, to the end of the year, \$15,000 was paid from sources outside the trust for the support and maintenance of D. The \$25,000 is considered an addition to corpus subject to the generation-skipping transfer provisions.

Example (5). H and W are the grantors of separate revocable generation-skipping trusts which were in existence on June 11, 1976, and not amended after that date. W dies in 1980 and under the provisions of her trust the corpus pours over into H's trust. If H dies before January 1, 1982, the entire trust is excluded under paragraph (b)(1) of this section from the generation-skipping provisions because H's trust failed to qualify under paragraph (b)(1)(ii) of this section. The fact that W died before 1982 is irrelevant, because her trust was added to a trust that never qualified under paragraph (b)(1)(ii).

(e) *Amendments to wills or revocable trusts.*—(1) *In general.* For purposes of this section, an amendment to a will or revocable trust in existence on June 11, 1976, will not be considered to result in the creation of, or an increase in the amount of, a generation-skipping transfer, where the amendment is—

(i) Basically administrative or clarifying in nature and only incidentally increases the amount transferred to a trust, or

(ii) Technical and designed to ensure qualification of a transfer for the applicable marital or charitable deduction for estate, gift, or generation-skipping tax purposes and only incidentally increases the amount transferred to a trust.

For purposes of determining whether a particular amendment to a will (or revocable trust) creates, or increases the amount of, a generation-skipping transfer, the effect of the will (or revocable trust) and of that amendment will be determined by reference to the facts as they exist on the date of death of the decedent.

(2) *Wills and trusts in existence on June 11, 1976.* For purposes of this section, a will or revocable trust will be considered in existence on June 11, 1976, if (i) the will or revocable trust was in existence on June 11, 1976, (ii) the will or revocable trust was revoked in its entirety by a new will or revocable trust that did not create or increase the amount of a generation-skipping transfer, and (iii) prior to the death of the testator or creator the new will or revocable trust is revoked in such a manner that, under local law, the document in existence on June 11, 1976, again controls the passing of property at death.

(3) *Examples.* The provisions of paragraph (e) (1) and (2) of this section may be illustrated by the following examples:

Example (1). An amendment decreases the number of trustees for a trust in existence on June 11, 1976. Although the amendment has the effect of lowering administrative costs and thus increasing the amount passing in a residuary generation-skipping transfer, it will be considered administrative in nature and will not prevent the trust from qualifying under paragraph (b) of this section.

Example (2). An amendment is made to a will in existence on June 11, 1976, that contains a formula marital deduction provision, to allow the estate to continue to obtain the maximum allowable estate tax marital deduction. Such an amendment does not prevent the will from qualifying under paragraph (b) of this section even though the amendment may incidentally produce an estate tax savings that increases the amount passing to a residuary generation-skipping trust.

Example (3). An amendment to the will of A revokes a bequest of \$10,000 to B and causes that amount to be added to a residuary trust that will make generation-skipping transfers. Such an amendment will be deemed to increase a generation-skipping transfer, unless B dies before A.

Example (4). On June 11, 1976, a will provided that an amount equal to the maximum allowable marital deduction would pass to the testator's spouse. After June 11, 1976, the will is amended by codicil to provide that the amount passing to the surviv-

ing spouse will not exceed one-half of the adjusted gross estate, even though a larger deduction may be allowable by reason of certain generation-skipping transfers or the application of section 2056(c)(1)(A)(i). As the amendment merely removes a potential ambiguity created by changes in the law subsequent to execution of the will (and does not change the original distribution of the estate) it will be considered clarifying in nature and will not prevent the will from qualifying under paragraph (b).

Example (5). On June 11, 1976, D's will provided that an amount equal to the maximum allowable marital deduction would pass to D's spouse. After June 11, 1976, the will is amended to provide that the marital share passing to D's spouse shall be the lesser of the maximum allowable marital deduction or that amount which will result in no estate tax liability for D's estate. The amendment is not considered clarifying in nature and may, therefore, prevent the will from qualifying under paragraph (b).

Example (6). On September 1, 1976, C executed a codicil to a will that was in existence on June 11, 1976. The codicil increased the amount of a generation-skipping transfer in the original will. On July 1, 1977, C executed a codicil revoking the prior codicil. The first codicil will be considered an amendment to a will in existence on June 11, 1976 which increased the amount of the generation-skipping transfer, even though it was subsequently revoked.

Example (7). On June 22, 1976, C executed a new will (as opposed to a codicil) revoking entirely a will in existence on June 11, 1976, and increasing the amount passing in one of two generation-skipping transfers. The second will is a new will that was not in existence on June 11, 1976, and neither instrument will qualify under paragraph (b) of this section.

Example (8). On June 15, 1976, C executed a new will (as opposed to a codicil) revoking entirely a will in existence on June 11, 1976. Each amount passing in a generation-skipping transfer under the new will is no greater than the amount that would have passed under the will in existence on June 11, 1976. If prior to C's death, C revokes the new will in such a manner that the document in existence on June 11, 1976, becomes subject to probate, the intervening instrument will not disqualify the original instrument for purposes of paragraph (b) of this section. If C revokes the new will by a later will republishing the original will in its entirety, the republication would not qualify the will under paragraph (b) unless local law would require the proof of the original document as C's will.

JEROME KURTZ,
Commissioner of Internal Revenue.

[FR Doc. 78-35688 Filed 12-21-78; 8:45 am]

[3710-08-M]

DEPARTMENT OF DEFENSE

Department of the Army

[32 CFR Part 505]

[Army Reg. 340-21]

PERSONAL PRIVACY AND RIGHTS OF INDIVIDUALS REGARDING PERSONAL RECORDS

Proposed Exemption

AGENCY: Department of Defense, Department of the Army.

ACTION: Proposed exemption rule.

SUMMARY: The Army proposes to amend § 505.9 by adding an exemption to the Department of the Army Privacy Act rules for proposed new system of records identified in the Supplementary Information below.

DATES: Comments must be received within 30 calendar days, on or before January 21, 1979.

ADDRESS: Send comments to The Adjutant General, Department of the Army, ATTN: DAAG-AMR-R, Forrestal Building, 1000 Independence Avenue, SW, Washington, DC 20314.

FOR FURTHER INFORMATION CONTACT:

Mr. Cyrus H. Fraker at the above address; telephone: (202) 693/0973.

SUPPLEMENTARY INFORMATION: The proposed exemption rule would apply to proposed new system of records A0402.01aDAJA, entitled General Legal Files, which is published in the FEDERAL REGISTER concurrently with this rule (see notices section). Exemption is needed as records from other exempted systems of records are sometimes submitted for legal review or other action. Copy of such records may be permanently incorporated into the General Legal Files as evidence of facts upon which a legal opinion or review was based. Exemption will ensure that such records continue to receive the same protection afforded them by exemptions granted to the system of records in which they were originally filed.

The Department of the Army rules have been published in the FEDERAL REGISTER in FR Doc. 77-28255 of September 28, 1977 (42 FR 51486) and amended in FR Doc. 78-490 of January 9, 1978 (43 FR 1336), FR Doc. 78-11264 of April 26, 1978 (43 FR 17821), and FR Doc. 78-24623 of August 31, 1978 (43 FR 38823).

This amendment is proposed under the authority of the Privacy Act of 1974, Pub. L. 93-579, 5 U.S.C. 552a.

MAURICE W. ROCHE,
Director, Correspondence and Directives, Washington Headquarters Services, Department of Defense.

DECEMBER 18, 1978.

§ 505.9 is amended by adding the following exemption rule. It should be inserted before exemption rule ID-A0501.08bDAMI (42 FR 51503), September 28, 1977.

§ 505.9 Exemption rules for Army systems of records.

EXEMPTED RECORD SYSTEMS (Specific Exemptions)

ID-A0402.01aDAJA.

SYSNAME—General Legal Files.

EXEMPTION—Those portions of this system of records falling within 5 U.S.C. 552a(k) (1), (2), (5), (6), and (7) may be exempt from the following provisions of Title 5 U.S.C. Section 552a: (c)(3), (d), (e)(1), and (f).

AUTHORITY—U.S.C. 552a(k) (1), (2), (5), (6), and (7).

REASONS—Various records from other exempted systems of records are sometimes submitted for legal review or other action. A copy of such records may be permanently incorporated into the General Legal Files system of records as evidence of the facts upon which a legal opinion or review was based. Exemption of the General Legal Files system of records is necessary in order to ensure that such records continue to receive the same protection afforded them by exemptions granted to the systems of records in which they were originally filed.

[FR Doc. 78-35524 Filed 12-21-78; 8:45 am]

[6560-01-M]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 65]

[FRL 1028-5]

STATE AND FEDERAL ADMINISTRATIVE ORDERS PERMITTING A DELAY IN COMPLIANCE WITH STATE IMPLEMENTATION PLAN REQUIREMENTS

Proposed Delayed Compliance Order for Sunmark Industries, a Division of Sun Oil Co. of Pennsylvania, Clermont, Ind.

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: U.S. EPA proposes to issue an Administrative Order to Sunmark Industries, a Division of Sun Oil Company of Pennsylvania. The Order requires the Company to bring its gasoline loading rack at Clermont, Indiana, (the Source) into compliance with APC-15, Section 4, part of the federally-approved Indiana State Implementation Plan (SIP). Because the Company is unable to comply with this regulation at this time, the proposed Order would establish an expeditious schedule requiring final compliance by July 1, 1979. Source compliance with the Order would preclude suits under the Federal enforcement and citizen suit provisions of the Clean Air Act (Act) for violation of the SIP regulation covered by the Order.

The purpose of this notice is to invite public comment and to offer an opportunity to request a public hearing on EPA's proposed issuance of the Order.

DATES: Written comments must be received on or before the thirtieth day of this notice and requests for a public hearing must be received on or before the fifteenth day from the date of this notice. All requests for a public hearing should be accompanied by a statement of why the hearing would be beneficial and a text or summary of any proposed testimony to be offered at the hearing. If there is significant public interest in a hearing, it will be held after twenty-one days prior notice of this date, time, and place of the hearing has been given in this publication.

ADDRESSES: Comments and requests for a public hearing should be submitted to Director, Enforcement Division, U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604. Material supporting the Order 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. Arthur E. Smith, Jr., Attorney, Enforcement Division, U.S. Environmental Protection Agency, 230 South Dearborn Street, Chicago, Illinois 60604, at (312) 353-2082.

SUPPLEMENTARY INFORMATION: Sunmark Industries, a Division of Sun Oil Company of Pennsylvania, owns a gasoline loading facility at Clermont, Indiana. The proposed Order addresses emissions from the gasoline loading facility, which is subject to APC-15, Section 4 of the Indiana Implementation Plan. The regulation limits the emissions of volatile organics (hydrocarbons) and is part of the federally-

approved Indiana State Implementation Plan. The Order requires the final compliance with the regulation by July 1, 1979, and the Source has consented to its terms. The Source has agreed to meet the Order's increments during the period of this informal rulemaking.

The proposed Order satisfies the applicable requirements of Section 113(d) of the Clean Air Act. If the Order is issued, Source compliance with its terms would preclude further EPA 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 provisions of the Act (Section 304) would be similarly precluded.

Comments received by the date specified above will be considered in determining whether EPA should issue the Order. Testimony given at any public hearing concerning the Order will also be considered. After the public comment period and any public hearing, the Administrator of EPA will publish in the *FEDERAL REGISTER* the Agency's final action on the Order in 40 CFR Part 65.

Dated: December 12, 1978.

JOHN MCGUIRE,
Regional Administrator,
Region V.

In consideration of the foregoing, it is proposed to amend 40 CFR Chapter I, as follows:

Part 65—Delayed Compliance Orders

1. By adding an entry to the table in § 65.190, *Federal Delayed Compliance Orders issued under Section 113(d) (1), (3), and (4) the Act*, to reflect approval of the following order:

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY REGION V

In the Matter of: Sunmark Industries, a Division of Sun Oil Company of Pennsylvania Clermont, Indiana. Proceeding pursuant to Section 113(d) of the Clean Air Act, as amended (42 U.S.C. Section 7413(d)), Order No. —.

This Order is issued this date pursuant to Sections 113(a), 113(d) and 114 of the Clean Air Act, as amended, 42 U.S.C. Section 7401 et seq. (Act). This Order contains a schedule for compliance, interim control requirements, and reporting requirements. Public notice, opportunity for a public hearing, and thirty (30) days notice to the State of Indiana have been provided pursuant to Section 113(d)(1) of the Act.

FINDINGS

1. On April 12, 1978, the United States Environmental Protection Agency (U.S. EPA) issued a Notice of Violation, pursuant to Section 113(a)(1) of the Act, to Sunmark Industries, a Division of Sun Oil Company of Pennsylvania (Sun Oil), upon a finding that

the Clermont Terminal, gasoline loading facility, was in violation of Indiana APC-15, Section 4, a part of the applicable Implementation Plan defined in Section 110(d) of the Act. This finding was based upon emission factor calculations derived from data submitted to U.S. EPA by the subject facility.

2. In satisfaction of Section 113(a)(4) of the Act, opportunity to confer with the Administrator's delegate was given to Sun Oil, and on April 27, 1978, an enforcement conference was held.

3. It has been determined that Sun Oil is unable to immediately comply with the applicable Implementation Plan.

After a thorough investigation of all relevant facts, including public comment, it is determined that the schedule for compliance set forth in this Order is as expeditious as practicable, and that the terms of this Order comply with Section 113(d) of the Act. Therefore, it is hereby Ordered:

ORDER

I. That Sun Oil will comply with the Indiana Implementation Plan regulation APC-15, Section 4, as approved by U.S. EPA on May 14, 1973, including a vapor collection and disposal/recovery system, in accordance with the following schedule on or before the dates specified therein.

A. In regard to the gasoline loading facility at Clermont, Indiana:

1. July 31, 1978—Sun Oil shall award contracts for the control equipment.

2. October 2, 1978—Sun Oil shall initiate on-site construction for the control equipment.

3. May 1, 1979—Sun Oil shall complete on-site construction.

4. July 1, 1979—Sun Oil shall achieve final compliance with the Indiana Implementation Plan regulation APC-15, Section 4, as approved by the U.S. EPA on May 14, 1973.

5. Sun Oil shall implement operation and maintenance procedures to maximize the control efficiency of the pollution control equipment.

II. That Sun Oil, Clermont Terminal, gasoline loading facility shall use the best practicable interim system of emission reduction so as to minimize hydrocarbon emissions; avoid any imminent and substantial endangerment to the health of persons; comply with the requirements of the applicable Implementation Plan insofar as it is able to; and, comply with the following interim requirements:

A. Sun Oil shall insert fill-pipes to the bottom of the loading compartment in a vertical position. Sun Oil shall control flow rate so as to minimize hydrocarbon emission.

B. Sun Oil shall minimize product spillage.

III. That Sun Oil, Clermont Terminal, gasoline loading facility, shall comply with the following emission monitoring and reporting requirements on or before the dates specified below:

A. *Emission Monitoring.* Sun Oil shall maintain a record of the amount of gasoline which travels through the loading facility. This shall include the volume and vapor pressure of the gasoline.

B. *Reporting Requirements.* 1. No later than fifteen (15) days after any date for achievement of an incremental step of final compliance, specified in this Order, Sun Oil shall notify U.S. EPA in writing of its compliance, or noncompliance and reasons

PROPOSED RULES

therefore, with the requirement. If delay is anticipated in meeting any requirement of this Order, Sun Oil shall immediately notify U.S. EPA in writing of the anticipated delay and reasons therefore.

2. A quarterly report shall be sent to the U.S. EPA reporting the progress of the program for installation of the control equipment and information required by paragraph III. A.

3. All submittals and notifications to U.S. EPA pursuant to this Order shall be made to Mr. Eric Cohen, Chief, Compliance Section, Enforcement Division, U.S. EPA, 230 South Dearborn Street, Chicago, Illinois 60604.

IV. Nothing herein shall affect the responsibility of Sun Oil to comply with State or local regulations, or other Federal regulation.

V. Sun Oil is hereby notified that its failure to achieve final compliance by July 1, 1979, at the Clermont Terminal, gasoline loading facility may result in a requirement to pay a noncompliance penalty under Section 120. In the event of such failure, Sun Oil will be formally notified, pursuant to Section 120(b)(3) and any regulations promulgated thereunder, of its noncompliance.

VI. Violation of any requirement of this Order shall result in one or more of the following actions:

A. Enforcement of such requirement pursuant to Section 113 (a), (b), or (c) of the

Act, including possible judicial action for an injunction and/or penalties and in appropriate cases, criminal prosecution.

B. Revocation of this Order, after notice and opportunity for a public hearing, and subsequent enforcement of Indiana Implementation Plan regulation APC-15, Section 4, in accordance with the preceding paragraph.

C. If such violation occurs on or after July 1, 1979, notice of noncompliance and subsequent action pursuant to Section 120 of the Act.

VIII. This Order is effective immediately.

Date _____

Administrator,
U.S. Environmental Protection Agency.

WAIVER OF RIGHTS TO CHALLENGE ORDER

Sun Oil, by the duly authorized undersigned, hereby consents to the provisions of this Order and waives any and all rights under any provisions of law to challenge this Order.

Date _____

(Signature of authorized representative of
Source)

[FR Doc. 78-35531 Filed 12-21-78; 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.

[6050-01-M]

ACTION

NATIONAL CONSUMER COOPERATIVE BANK FEDERAL INTERAGENCY TASK FORCE

Public Meetings

ACTION: Notice of public meetings.

SUMMARY: The Interagency Task Force on the National Consumer Cooperative Bank will be holding open public meetings for the purpose of soliciting input on issues related to the Bank. The Task Force is subdivided into five working Subcommittees, each of which will chair a session as follows.

DATE, TIME AND LOCATION:

Date, time and Subcommittee

Tues., Jan. 9, 1979 9:00 am—I Internal Procedures; 1:00 pm II Eligibility & Priorities.
Wed., Jan. 10, 1979 9:00 am—III Finance & Lending Policies; 1:00 pm—IV Self Help Development Fund.
Thurs., Jan. 11, 1979 9:00 am—V Technical Assistance; 1:00 pm General Bank Issues.

The location for all sessions will be the New Executive Office Building, Room 2008, 17th and Pennsylvania Aves., N.W., Washington, D.C. 20503.

FOR FURTHER INFORMATION CONTACT:

Coop Bank Work Group, ACTION, Room M-203, 806 Connecticut Ave., N.W., Washington, D.C. 20525, (202) 254-5101.

SUPPLEMENTARY INFORMATION: The Interagency Task Force consists of representatives of 11 Federal departments and agencies. It is responsible for the preparation of recommendations and proposals for implementation of the National Consumer Cooperative Bank Act (Pub. L. 95-351) for submission to the Board of Directors of the Bank, which will be appointed by the President, and which will have final responsibility for decisions relating to the policies and operations of the Bank. The Task Force has established five interagency subcommittees, with responsibilities in the areas noted above.

Draft versions of each Subcommittee's written submission to the Task Force will be available to the public by writing to the above address. Copies will not be available before the first week of January. Organizations and individuals interested in attending the public meetings are encouraged to

review the drafts and take advantage of this opportunity to raise issues about the Bank before the final version of the Task Force recommendations are submitted to the Bank's Board of Directors.

Issued in Washington, D.C., on December 14, 1978.

SAM BROWN,
Director, ACTION.

[FR Doc. 78-35569 Filed 12-21-78; 8:45 am]

[3410-02-M]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[TIPS Docket No. 31]

THOMAS B. HALL, JR., AND MARVIN E. INGE, JR., VIRGINIA DARK-FIRED TOBACCO GROWERS' MARKETING ASSOCIATION, INC., AND PLANTERS WAREHOUSE

Postponement of Hearing Regarding Application for Expansion of Tobacco Inspection and Price Support Services on the Designated Market at Kenbridge, Virginia, to All Types of Tobacco

Notice is hereby given of a postponement, not to exceed 60 days, of a public hearing for expansion of tobacco inspection and price support services on the designated market at Kenbridge, Virginia to all types of tobacco. The original hearing was scheduled to be held in the Conference Room of the Agricultural Building, Commerce Street, Kenbridge, Virginia 29344, at 10 a.m., e.s.t., on October 26, 1978. A postponement was granted for good cause shown upon the application of Mr. Thomas B. Hall, Jr., T/A Virginia Dark Fired Tobacco Growers' Marketing Association, Inc., Farmville, Virginia, and Mr. Marvin E. Inge, Jr., T/A Planters Warehouse, Blackstone, Virginia. Such public hearing will be rescheduled if necessary, and conducted pursuant to the concurrent and identical policy statements and regulations governing the extension of tobacco inspection and price support services to new markets and to additional sales on designated markets (37 FR 24693, June 18, 1978.)

Dated: December 18, 1978.

P. R. "BOBBY" SMITH,
Assistant Secretary for
Marketing Services.

[FR Doc. 78-35577 Filed 12-21-78; 8:45 am]

[3410-05-M]

Office of the Secretary

1979 UPLAND COTTON PROGRAM

Determinations Regarding Proclamation of the 1979-Crop National Program Acreage and Voluntary Reduction Percentage for Upland Cotton

AGENCY: Agricultural Stabilization and Conservation Service.

ACTION: Notice of Determination of the 1979-Crop National Program Acreage and Voluntary Reduction Percentage for Upland Cotton.

SUMMARY: The purpose of this notice is to determine and proclaim with respect to the 1979-crop of upland cotton (referred to as "cotton"), the national program acreage and voluntary reduction percentage. These determinations are required to be made by the Secretary in accordance with provisions of the Agricultural Act of 1949, as amended by the Food and Agriculture Act of 1977 and the Act of May 15, 1978, (referred to as the "Act"). The Act requires that the national program acreage and voluntary reduction percentage for the 1979 crop of cotton be announced no later than December 15, 1978. This notice is needed to satisfy statutory requirements.

EFFECTIVE DATE: December 22, 1978.

ADDRESS: Production Adjustment Division, ASCS-USDA, 3630 South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT:

Charles V. Cunningham (ASCS)
(202) 447-7873.

SUPPLEMENTARY INFORMATION: A notice that the Secretary was preparing to make determinations with respect to the 1979-crop program provisions for upland cotton was published in the FEDERAL REGISTER on Sep-

tember 1, 1978 (43 FR 39117¹), in accordance with 5 U.S.C. 553. A total of 61 comments were received, 34 from individual producers, 4 from multiproducer petitions, 5 from cotton farm organizations, 7 from general farm organizations, 5 from nonfarm public and 6 from ASC county committees. Nine comments were received related to the national program acreage. Four recommended that the national program acreage be set at the statutory minimum of 10 million acres; one recommended 10.2 million acres; three recommended 10.5 million acres; and one recommended 12 million acres. Five comments were received relative to the voluntary reduction percentage. One recommended a 10 percent reduction, one a 15 percent reduction, one a 20 percent reduction, and two were against any voluntary reduction. All comments received were duly considered by the Secretary within the statutory authority.

It is essential that these decisions be made effective as soon as possible since the proclamation of the national program acreage and voluntary reduction percentage is required to be made not later than December 15, 1978. Therefore, the Secretary has made the following determinations:

FINAL DETERMINATIONS

1. *National Program Acreage.* It is hereby proclaimed that the national program acreage for the 1979-crop of cotton shall be 10,634,181 acres determined in accordance with Section 103 (f)(7) of the Act. This is the acreage determined needed in 1979, based on the weighted national average of farm payment yields, to produce the estimated domestic consumption and exports, less imports plus an adjustment to bring stocks to the desirable level. The computation of the national program acreage is as follows:

a. Estimated domestic consumption, 1979-80 (480-lb. net wt. bales).....	6,200,000
b. Plus estimated exports, 1979-80, (480-lb. net wt. bales).....	5,500,000
c. Minus estimated imports, 1979-80, (480-lb. net wt. bales).....	15,000
d. Plus adjustment to bring stocks to desirable level (480 lb. net wt. bales).....	500,000
e. Times 480 lbs. per bale (lbs.).....	5,848,800,000
f. Divided by estimated weighted national average of farm program yields (lbs./acre).....	550
g. Equals: 1979, National Program Acreage (acres).....	10,634,181

2. *Voluntary Reduction Percentage.* In accordance with Section 103(f)(9) of the Act, it is hereby determined and proclaimed that producers who voluntarily reduce their 1979 cotton acreage from that planted and considered planted in 1978 by at least 15 percent and who comply with other program requirements shall be guaranteed any

deficiency payments on the normal production from their entire planted acreage. In applying the voluntary reduction for 1979, the 1978 cotton acreage planted and considered planted shall be the sum of:

- The planted acreage, excluding:
 - any acreage that failed and was not replanted during the normal planting period, and,
 - any acreage that was planted and subsequently destroyed for designation as set-aside or diverted acreage.
- The approved prevented planted acreage.
- The larger of:
 - The acreage voluntarily reduced in 1978 from 1977 (total of planted and approved prevented planted acreage), not to exceed the 1978 voluntary reduction of 20 percent, or
 - the acreage diverted under the 1978 voluntary cotton diversion program.
- The increase in the normal crop acreage for the farm in 1979 resulting from a change from skip-row planting in 1978 to solid planting in 1979 with a consequent reduction in the farm established (payment) yield.

The acreage determined needed in 1979 is 10,634,181 acres. In 1978, there were 12,661,000 acres harvested and considered harvested. Thus, a reduction of 2,026,819 acres, or 15 percent, is needed in 1979, calculated as follows:

1. Estimated 1978 harvested acreage.....	12,211,000
2. Plus estimated considered harvested acreage.....	450,000
3. Equals: Harvested and considered harvested acreage.....	12,661,000
4. Minus 1979 national program acreage.....	10,634,181
5. Equals: Acreage reduction needed in 1979.....	2,026,819
6. Divided by estimated 1978 harvested and considered harvested acreage.....	12,661,000
7. Equals: 1979 reduction percentage (rounded to nearest 5 percent).....	15

NOTE.—An approved impact analysis statement is available from Charles V. Cunningham (ASCS), (202) 447-7873.

NOTE.—The ASCS, to meet the requirements of the National Environmental Policy Act (Pub. L. 91-190, 42 U.S.C. 4321, et seq.) has determined that the impact of the 1979 upland cotton program on the human environment is not significantly different from the impact discussed in an environmental impact assessment on file for the 1978 program, nor from those impacts presented in the impact analysis statement on the 1979 program, and, therefore, no additional environmental impact statement is necessary.

Signed at Washington, D.C. on December 15, 1978.

BOB BERGLAND,
Secretary,

[FR Doc. 78-35360 Filed 12-15-78; 3:56 am]

[3410-03-M]

Science and Education Administration

NATIONAL AGRICULTURAL RESEARCH AND EXTENSION USERS ADVISORY BOARD

Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463, 86 Stat. 770-776), the Science and Education Administration announces the following meeting:

NAME: National Agricultural Research and Extension Users Advisory Board.

DATE: January 8 and 9, 1979.

TIME: 9:00 a.m.

PLACE: Room 330, GHI Building, 500 12th Street, S.W., Washington, D.C.

TYPE OF MEETING: Open to the public. Persons may participate in the meeting as time and space permit.

COMMENTS: The public may file written comments before or after the meeting with the contact person below.

PURPOSE: To organize this new Board and initiate measures to develop independent advisory opinions on the food and agricultural sciences.

CONTACT PERSON FOR AGENDA AND MORE INFORMATION:

Dr. James Nielson, Executive Director of the Board, Science and Education Administration, U.S. Department of Agriculture, Washington, D.C. 20250, telephone: 202-447-8662.

Done at Washington, D.C., this 19th day of December, 1978.

JAMES NIELSON,
Executive Director, National Agricultural Research and Extension Users Advisory Board.

[FR Doc. 78-35662 Filed 12-21-78; 8:45 am]

[3410-03-M]

JOINT COUNCIL ON FOOD AND AGRICULTURAL SCIENCES

Meeting

According to the Federal Advisory Committee Act of October 6, 1972 (Public Law 92-463, 86 Stat. 770-776), the Science and Education Administration announces the following meeting:

NAME: Joint Council on Food and Agricultural Sciences.

DATE: January 10, 11, and 12, 1979.

TIME: 1:00 p.m. on January 10 and 9:00 a.m. on January 11 and 12.

PLACE: Room 330, GHI Building, 500 12th Street, SW, Washington, D.C.

¹The original document was submitted as a proposal and appear in the Proposed Rules section of the Register.

TYPE OF MEETING: Open to the public. Persons may participate in the meeting as time and space permit.

COMMENTS: The public may file written comments before or after the meeting with the contact person below.

PURPOSE: To receive reports from several ad hoc and standing subcommittees and initiate further measures to foster coordination of the agricultural research, extension, and teaching activities of the Federal, State, and private sector.

CONTACT PERSON FOR AGENDA AND MORE INFORMATION: Dr. James Nielson, Executive Director of the Joint Council, Science and Education Administration, U.S. Department of Agriculture, Washington, D.C. 20250, telephone 202-447-8662.

Done at Washington, D.C., this 19th day of December, 1978.

JAMES NIELSON,
Executive Director, Joint Council on Food and Agricultural Sciences.

[FR Doc. 78-35529 Filed 12-21-78; 8:45 am]

[6320-01-M]

CIVIL AERONAUTICS BOARD

AIR EXPRESS INTERNATIONAL AIRLINES, INC.

Application for an All-Cargo Air Service Certificate

DECEMBER 15, 1978.

In accordance with Part 291 (14 CFR 291) of the Board's Economic Regulations (effective November 9, 1978), notice is hereby given that the Civil Aeronautics Board has received an application, Docket 34028, from Air Express International Airlines, Inc. incorporated in Delaware with corporate headquarters at Stamford, Connecticut, for an all-cargo air service certificate to provide domestic cargo transportation.

Under the provisions of § 291.12(c) of Part 291, interested persons may file an answer in opposition to this application on or before January 12, 1979. An executed original and six copies of such answer shall be addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. It shall set forth in detail the reasons for the position taken and must relate to the fitness, willingness, or ability of the applicant to provide all-cargo air service or to comply with the Act or the Board's orders and regulations. The answer shall be served upon the applicant and state the date of such service.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35670 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Docket 33237]

CALIFORNIA-ARIZONA LOW FARE ROUTE PROCEEDING

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 on March 6, 1979, at 9:30 a.m. (local time), in Room 6 N 10 (North Corridor), Federal Office Building, 880 Front Street, San Diego, California 92188, 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 November 14, 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., December 18, 1978.

FRANK M. WHITING,
Administrative Law Judge.

[FR Doc. 78-35671 Filed 12-21-78; 8:45 am]

[6320-01-M]

CONNER AIR LINES, INC.

Application for an All-Cargo Air Service Certificate

DECEMBER 15, 1978.

In accordance with Part 291 (14 CFR 291) of the Board's Economic Regulations (effective November 9, 1978), notice is hereby given that the Civil Aeronautics Board has received an application, Docket 33972, from Conner Air Lines, Inc. of Miami Springs, Florida for an all-cargo air service certificate to provide domestic cargo transportation.

Under the provisions of § 291.12(c) of Part 291, interested persons may file an answer in opposition to this application to this application on or before January 12, 1979. An executed original and six copies of such answer shall be addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. It shall set forth in detail the reasons for the position taken and must relate to the fitness, willingness, or ability of the applicant to provide all-cargo air service or to comply with the Act or the Board's orders and regulations. The answer shall be served upon the applicant and state the date of such service.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35669 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Order 78-12-93; Docket 32702]

DELTA AIR LINES, INC.

Order To Show Cause

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 14th day of December 1978. Application of Delta Air Lines, Inc. for amendments of its certificates of public convenience and necessity for Routes 8, 24, and 54.

On May 18, 1978, Delta Air Lines filed an application in Docket 32702 to authorize it to provide nonstop transportation between Kansas City, Missouri, on the one hand, and Chicago, Illinois, and Denver, Colorado, on the other hand. It simultaneously moved to consolidate its application in Docket 32528.

Delta has authority at each of the three points mentioned above, but, due to its route structure, it is prohibited from operating nonstop service between them.¹

On November 16, 1978, by Order 78-11-54, we proposed to remove the restrictions on Braniff, Continental, Frontier and TWA in the Kansas City-Chicago/Denver markets. We inadvertently failed to include Delta in this proposal. Since its application in this docket presents us with similar issues to those we addressed in Order 78-11-54, we tentatively conclude, for the same tentative reasons stated in that order, that it is consistent with the public convenience and necessity to amend Delta's certificate for Routes 8, 24 and 54 so as to authorize nonstop transportation between Kansas City, on the one hand, and Chicago and Denver, on the other.^{2,3}

¹We have proposed to realign its routes in Order 78-4-109 and to grant it one-stop authority in the Kansas City-Chicago market. Delta route realignment, April 19, 1978. Our proposal here would preempt that proposal and require a corresponding change in the final realignment order. See also Order 78-11-54, fn. 7.

²We will deny Delta's motion to consolidate its application into Docket 32528 for two reasons. Technically, we closed that docket by virtue of our dismissal of United's application in Order 78-11-54. More fundamentally, we choose not to amend that order, but to issue a separate show-cause order for Delta, as more orderly and in conformance with the due process requirements of granting notice and an opportunity to be heard to any objectors.

³We further tentatively find that Delta is a citizen of the United States within the meaning of the Act and is fit, willing and able to perform the air transportation proposed here. We also tentatively find that our action is not a major Federal action significantly affecting the quality of the human environment within the meaning of section 102(2)(C) of the National Environmental Policy Act of 1969 or a "major regulatory action" requiring an energy statement under Part 313 of our Procedural Regulations.

We will give interested persons 20 days from the date of service of this order to show cause why the tentative findings and conclusions stated here should not be made final. We expect such persons to support their objections, if any, with detailed answers specifically reciting the tentative findings and conclusions to which they object. If the objector requests an oral evidentiary hearing he should state, in detail, why such a hearing is necessary and what relevant and material facts he would expect to establish through such a hearing that cannot be established in written pleadings. We will not entertain general, vague or unsupported objections. Answers should be filed within 5 days after the date for filing objections.

Accordingly, 1. We direct all interested persons to show cause why we should not issue an order making final the tentative findings and conclusions stated here and amending Delta's certificates of public convenience and necessity for Routes 8, 24 and 54 so as to authorize nonstop air transportation between Kansas City, on the one hand, and Chicago and Denver, on the other;

2. We deny Delta's motion to consolidate into Docket 32528 its application filed in Docket 32702;

3. We direct any interested person having objection to the issuance of an order making final the proposed findings or conclusions made here to file with us no later than January 8, 1979, and serve upon all persons listed in paragraph 7, a statement of objections together with a summary of testimony, statistical data, and other evidence relied upon to support the stated objections; * answers will be due no later than January 15, 1979;

4. If timely and properly supported objections are filed, we will fully consider the matters and issues raised by the objections before we take further action;

5. In the event no objections are filed, we will deem all further procedural steps to have been waived and we may proceed to enter an order in accordance with the tentative findings and conclusions stated here;

6. For purposes of computing license fees, we direct Delta to estimate its annual gross transport revenue increase, for the first full year of operations, resulting from the modified authority tentatively granted by this order; and

7. We will serve a copy of this order upon the Mayors of the Cities of Chicago, Denver and Kansas City, the directors of O'Hare Field, Stapleton International Airport, Kansas City International Airport, the Governors of

the States of Illinois, Colorado, Kansas and Missouri, the heads of the Departments of Transportation of the States of Illinois, Colorado, Kansas and Missouri, and on Braniff Airways, Continental Air Lines, Delta Air Lines, Frontier Airlines, Trans World Airlines, and United Air Lines.

We will publish this order in the FEDERAL REGISTER.

By the Civil Aeronautics Board: *

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35672 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Order 78-12-106; Docket 28848, et al.]

IMPROVED AUTHORITY TO WICHITA CASE, ET AL.

Opinion and Order

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 14th day of December, 1978.

In the matter of Improved Authority to Wichita Case (Docket 28848); Las Vegas-Dallas/Fort Worth Nonstop Service Investigation (Docket 29445); Memphis-Twin Cities/Milwaukee Case (Docket 29186); Midwest-Atlanta Nonstop Service Investigation (Docket 28115); Ohio/Indiana Points Nonstop Service Investigation (Docket 21162); Phoenix-Des Moines / Milwaukee Route Proceeding (Docket 28800).

By the Board: At issue in all six cases before us is whether the Board should adopt a broad policy of granting multiple permissive authority to all qualified applicants in markets able to support some service. The general question of reducing regulatory barriers to entry has been at the heart of the intensive congressional examination of air transportation that culminated recently in the Airline Deregulation Act of 1978. At the Board, efforts to reduce those barriers and to strengthen competition within the industry have been a central regulatory interest for some time. In formal cases, the first steps toward freer entry were taken about a year ago when the Board adopted a more liberal approach to route awards by licensing two or more new applicants in some markets and by giving them the flexibility to enter or leave the new routes without Board permission. In these cases, it minimized the significance of revenue diversion from incumbent airlines as a reason for restricting entry, and found that the public would benefit from multiple awards whether they resulted in actual or potential competition even if the market could not support all the service being authorized. Nevertheless,

* All members concurred.

it continued to limit awards to the number that given markets might reasonably be predicted to sustain and continued also to engage in carrier selection, by certificating some airlines and denying the applications of others. *Greenville/Spartanburg-Washington/New York Subpart M Case*, Order 77-10-1; *Cincinnati-Washington Subpart M Proceeding*, Order 77-10-4, *Improved Authority to Wichita Case* Order 78-3-78, and *Midwest-Atlanta Nonstop Investigation*, Order 78-7-137. Later the Board went beyond limited liberalizations of this kind to consider licensing all qualified applicants on a permissive basis in markets able to support some service. That approach was adopted in a number of specific instances, the *Piedmont Entry to Boston Case*, Order 78-97, *Oakland Service Case*, Orders 78-4-121 and 78-9-96, the *Chicago-Midway Low Fare Route Proceeding*, Order 78-7-40, and 78-8-203, and *Philadelphia-Bermuda Nonstop Proceeding*, Docket 32786, now awaiting action by the President.

In the present group of six cases we are in the process of deciding whether to apply a multiple permissive entry policy more generally throughout the system. In each of them, partial awards have already been made consistent with the moderate liberalization mentioned earlier, and the applications of those carriers that were not licensed in the initial round have been deferred pending a determination of whether the Board should go further—either by adopting a general policy of licensing all qualified applicants or by adding to the number of carriers already licensed on the basis of the narrower criteria used in making the earlier awards. To encourage the fullest possible public participation, parties and non-parties alike were invited to submit written comments on the broad policy and legal ramifications of multiple permissive entry and related options, and a joint omnibus oral argument was held for two full days on these questions.

On July 21, 1978, the Board used the *Las Vegas-Dallas/Ft. Worth Nonstop Service Investigation* as a forum for announcing its conclusion that:

[I]n markets able to support some service, a general regulatory policy of general permissive licensing of all qualified applicants, will in most, and possibly in all instances best meet the transportation goals of the Federal Aviation Act for the present and foreseeable future. Order 78-7-116, at 2.

We also stressed that if and when such a policy were adopted, it would be effective only if extended to "the core of the system" and made broad enough (and carried out rapidly enough) to create substantial competitive opportunities for all segments of the industry. However, we were not prepared to adopt a universal policy if

* Since we have provided for the filing of objections, we will not entertain petitions for reconsideration of the show-cause order.

multiple entry because of the possibility that a more restrictive approach might be preferable in certain limited situations, and indeed were unprepared to adopt any general policy until we had more carefully examined its environmental consequences and considered further our legal authority to put it into effect on a systemwide basis.

With the passage of the Airline Deregulation Act, there has been a profound change in the decisional environment. First, the debate over the long-term value and desirability of multiple permissive awards in domestic and overseas markets is over. The new Act's most far-reaching contribution is to eliminate by 1982 all barriers to entry by "fit, willing, and able" carriers, and, by the following year, to end the regulation of domestic rates. Congress has thereby accepted our underlying rationale for multiple permissive awards: (1) the industry is not a natural monopoly or oligopoly; (2) reliance on competition and the disciplines of the marketplace will provide consumers a much wider array of price and service options and produce a more economic and efficient system than one developed through continued Board efforts to predict in advance the level of demand in given markets, limit the number of awards to projected demand, and choose the "best" of the applicants; and (3) whatever need there may have been to protect the fledgling subsidized industry from "excessive competition" in the early years of the regulatory regime, in today's mature, demand-based network competition will work as well as in most unregulated sectors of the economy.

The assurance of an essentially open system in three years allays the expressed concerns of some parties about a policy of multiple permissive entry under the old Act. For example, National has argued that as long as the licensing requirement exists, airlines will continue to treat certificates as having substantial capital value and will engage in uneconomic and mutually destructive operations to protect them. This will happen, it has insisted, even if the Board licenses all qualified applicants and thereby reduces the value of certificates because airlines will act on a perceived risk that unused authority will one day be administratively or legislatively revoked. The Board has already found it far-fetched to assume that if certificates have no significant present value, carriers would nonetheless systematically introduce and maintain uneconomic operations in the hope that the Board's liberalized entry policy will be radically altered at some future time. *Las Vegas-Dallas/Ft. Worth* case, Order 78-7-116, p. 4. Now that Congress has mandated open entry after

three years and a more competitive system in the transitional period, National's concern should be completely set to rest.¹

Other parties have worried that the Board might, by proceeding on a case-by-case basis, open only a small part of the system to vigorous competition and leave the rest of it essentially closed, and that if this were done haphazardly (e.g., without favoring smaller carriers) it could aggravate the advantages that 40 years of regulation have given the large trunks and create perverse incentives for them to engage in predatory behavior in the "open" markets while most of their existing routes remain protected. We have been sensitive to this danger, and as noted, have emphasized that any Board policy of multiple awards, should one be adopted, would extend to the core of the system; but the fact that the entire system will be open in three years regardless of what the Board does in the interim, and the inescapable spillover effect of this ultimate liberalization on the interim period, guarantees that ample competitive opportunities will be available to all classes of carriers and that airline managements can plan for the future with certain knowledge that this is the kind of environment in which they will be operating.

Another frequently expressed concern has been that permissive authority, even if coupled with multiple licensing, would give smaller communities less assurance of continued and stable service than would "mandatory" authority. We have rejected this argument before, pointing out that the air transportation system has been essentially permissive for decades—with airlines having great flexibility to operate between and among points on the same segment of a certificate and the Board being generally sympathetic to requests by carriers for permission to withdraw from points where they operate at a serious loss. In fact, it is clear that effective service has depended all along not on mandatory authority but on sufficient demand for the service and vigorous competition. Increased competition, both actual and potential, is also the approach most likely to insure improved service in the

future (in the broader sense of lower prices as well as ample frequencies).

The new Act recognizes these facts. It abolishes mandatory authority in the sense that carriers are no longer required to get Board permission before ceasing service at a point, although they do have an obligation to provide notice of their intention to do so.² Instead, to make sure that the loosening of regulatory constraints does not result in a downgrading of service to small communities, Congress has established two specific programs aimed at preserving such services. First, the "unused authority" provision (Section 401(d)(5)(A)) is designed to get effective nonstop service into a market almost automatically if an incumbent in that market is not using its authority or is providing less than a minimum level of service (5 weekly nonstop round trips) for a specified period.³ This provision, however, comes into play only if there is a new carrier willing to operate substitute service. Already, 22 airlines have been authorized to enter 252 markets under this program. A second provision, section 419, is explicitly designed to guarantee "essential air transportation" to small communities for at least 10 years, if necessary through a system of direct subsidy. While Congress has left it up to the Board to define "essential air transportation" for each eligible point, it has specified that it means, at a minimum, two daily round trips five days per week or the aggregate level of service provided at the point in 1977, whichever is less.⁴ The program extends to all currently certificated points as well as points that were deleted from the route map after July 1, 1968, but which the Board decides to make eligible under the program.

The promise of the virtual end of entry controls by 1982 creates certain imperatives for the regulatory climate in the interim. In essence, our role in route cases is now to determine the proper manner and pace for phasing out regulatory barriers to entry—or, more specifically, to decide whether all qualified applicants should be licensed in any given market or whether one or more of them should be given a head start of three years or less. In

¹Under the new Act, dormant authority in smaller markets is subject to suspension in some circumstances when "replacement" authority is given to a new applicant. Our experience with the "unused authority" program so far suggests that it will lead to suspension in only a minor proportion of small "dormant" markets, which in turn represent an insignificant proportion of the total dormant authority that now exists in the system. To cite specific figures, by mid November the Board had granted new nonstop authority in 238 markets, and suspended incumbents in only 23 of them. In the great majority of cases, no one argued for the suspension of the incumbents.

²For the first time, carriers are also obligated to give notice of their intention to reduce service below a specified minimum. Other constraints on their ability to withdraw from markets are discussed below.

³Another "unused authority" provision, Section 401(d)(5)(D), applies to generally larger markets (those with two or more active nonstop carriers). Under this second provision, the Board is given some discretion to turn down a new applicant, but only if it can overcome the rebuttable presumption that a grant of the application is consistent with the public convenience and necessity.

⁴A different standard applies in Alaska.

planning the transition the Board cannot ignore the obvious, namely that the industry cannot go from a scheme of tight regulation during the next three years to open entry all at once; if the transition is to be a smooth one, the Board must begin a substantial liberalization as soon as possible. To make sure that this happens, Congress has made important changes in our current legislative mandate. Apart from special provisions designed to accomplish rapid expansions of route authority (e.g., the "unused authority," "automatic entry" and "restriction removal" programs), the certification standards have been changed to substantially restrict the Board's discretion to limit competition.

For example, the new declaration of policy for domestic and overseas transportation, Section 102(a), stresses "maximum reliance on competitive market forces and on actual and potential competition to provide needed transportation and foster efficiency, innovation, and low prices"; it also encourages entry into the industry by new carriers, entry into new markets by existing airlines, and more growth opportunities for small carriers.⁶ Coupled with this change in the policy statement, by which the Act defines the public convenience and necessity and the public interest, is a reversal in the burden of proof. A carrier need no longer prove that the transportation covered by its application is required by the public convenience and necessity; instead, opponents must now show that the transportation is *not consistent* with the public convenience and necessity and the Board in turn can deny the authority only if it finds, by a preponderance of the evidence, that granting it is not consistent with the public convenience and necessity.

In short, the net effect of the new Act is to confirm and strengthen our earlier conclusion that a general policy of multiple permissive licensing is the approach likely to produce the greatest transportation benefits.

One of the common arguments against this policy is that it will lead to greater industry concentration because big carriers have advantages that are difficult to overcome, such as large route systems that give them access to much more "feed" traffic to funnel through and support oper-

ations in new markets, and "deeper pockets," or superior capital resources with which to acquire new equipment and undertake promotional and developmental activities. Therefore, the argument goes, unless the Board is willing to see proportionately fewer carriers amass a proportionately larger share of industry revenues it must phase out regulatory controls in a way that favors smaller carriers. (For example, by opening the large trunklines' systems to competition first or by giving smaller carriers a head start in new markets).

While this argument has some surface appeal, it cannot withstand close scrutiny. In the first place, a carrier's financial strength and ability to attract capital cannot be equated with its size. The efficiency and profitability of its operations are ordinarily far more important to the investment community than its gross revenues, and in the airline industry, where economies of scale are limited and assets are mobile, there has historically been little direct relationship between profitability and efficiency, on the one hand, and size, on the other. (We recall a rather dramatic example two or three years ago when Pan American and TWA, two industry giants, were in a precarious financial position that left them far less able to attract equity capital than much smaller carriers—like Braniff or Western—could with their more profitable operations.)

Second, we see no serious danger that the superior traffic flows available to the large trunks will systematically deprive smaller operators of significant route opportunities or throttle their development as healthy competitors. We do not mean to suggest that feed traffic has no competitive value; on the contrary, the ability to integrate traffic from a number of points over a single route can bring important costs savings to carriers and improved benefits to the public, in the form of more service in local markets than they could sustain without backup traffic flows and single-plane flights to the beyond points that generate this flow. To some extent, this advantage may represent a true economy of integration that—all else being equal—should be encouraged.

But these economies of integration are often offset by other important advantages that smaller airlines can achieve and have achieved through specialization. For example, by developing regional service patterns, they can make optimal use of aircraft suited to that particular service without having to accommodate markets of sharply different sizes and characteristics; at the same time, they have more flexibility to tailor their services to the needs of the regional markets and

achieve a better on-time record by avoiding delays on distant legs of the same flight.⁶

As the air transportation system opens to free entry, the large carriers' advantage in feed traffic may well be reduced as their entire systems are subjected to competitive pressures from other carriers. But it seems clear that in some situations large integrated route systems will allow big carriers to win the competitive battle against the more specialized airlines with relatively homogeneous networks, while in others, the reverse will be true. We cannot predict which form of service is likely to predominate, and see no reason why we should prescribe one or the other of these forms rather than let the forces of the marketplace determine which pattern or combination of patterns is best in given circumstances. The fact is that smaller carriers, often lacking meaningful resources of feed traffic, have managed to compete very successfully against the largest carriers in the industry, and that far from being intimidated at the prospect, are begging for the chance to compete against large carriers in the future. Varying forms of service now coexist in numerous markets and as a general matter we see no need for Board protection to assure that they continue to do so.

Finally, as we have noted on a number of occasions, this is a particularly favorable time to move to a much more competitive environment without creating short run instability. The industry as a whole, and its local service and smaller trunkline segments in particular, are in sound financial condition; airlines do not have excess aircraft to dump indiscriminately into new markets even if they were otherwise willing or able to maintain loss operations in a predatory effort to undermine competition; and capital markets are not likely to support widespread uneconomic services of that kind. So even if some airlines were to engage in predatory behavior in some individual markets, there is no threat to the overall system or any significant part of it.⁷ *Las Vegas-Dallas Fort Worth Nonstop Service Investigation*, Order 78-7-116, pp. 4-5.

Despite the new Act, however, we are not prepared to conclude that a general policy of multiple discretionary entry, if adopted, should be ap-

⁶The actual language of the policy statement (Section 102(a)(10)), calls on the Board to encourage "the continued strengthening of small air carriers so as to assure a more effective, competitive airline industry." The Conference Committee Report makes it clear that this is not intended to protect them from competition but to give them new route opportunities "and not restrict them solely because they have historically had operations limited in area or extent."

⁶See the Kahn-Hydemann Correspondence on Automatic Market Entry submitted to the Aviation Subcommittee of the House Public Works and Transportation Committee on March 6, 1978, and the Oakland case, Order 78-9-96, p. 41.

⁷Both the Board and the Justice Department have tools available for dealing with individual instances of predatory behavior. See Section 411 of the Federal Aviation Act, as amended, and Section II of the Sherman Act.

plied universally. There might still be circumstances in which the public interest may be better served by giving only one or less than all qualified applicants immediate authority. (The Act obviously contemplates this possibility by retaining for three years a public convenience and necessity standard for route awards.)

For example, it is at least arguable that in some small markets, where no service is feasible without an initial developmental effort or where demand is just on the verge of being able to support service, one airline should be given temporary protection from competition, in the first case to provide it with the incentive to make the developmental investment and in the second to make sure that service is not delayed because potential entrants are scared off by multiple authorizations and the prospect of immediate competition.⁸ Accordingly, parties will continue to have an opportunity to demonstrate in individual cases that a multiple licensing policy should not apply in unusual factual circumstances.

LEGAL ISSUES

Much of the opposition to multiple entry has been directed at our legal authority to adopt such a policy. The Board has already made extensive findings in various cases to show that we do have the authority⁹ and no purpose would be served in repeating them here. Nonetheless, it is worth pointing out that whatever doubts may have remained, are put to rest by the new Act.

For example, National, among others, has argued on the basis of the language of the old Act that the Board has an obligation to limit awards to the number it predicts a market can support and therefore to engage in carrier selection. Its reasoning was: (the original) Section 401(d) ties certification to individual applications; the determination of a need for service cannot be separated from the identity of the carrier that is to provide it; and once the "documented need" has been satisfied in full no additional carrier can be licensed because the public convenience and necessity can no longer be said to "require" the transportation

covered by its application, which must accordingly be denied. We have rejected this interpretation largely because it is grounded on an unduly narrow and unreasonable understanding of the public convenience and necessity "requirement." That test, which continues to apply to foreign air transportation, was never intended to limit the grant of licenses to situations where an immediate demand for additional service exists. We have argued that it is broad enough to permit us to find that multiple permissive authorizations are required because competition, both actual and potential, is necessary to the advancement of other statutory goals, including the optimal development of an air transportation system and the promotion of efficient service at reasonable prices. These assumptions about the value of competition have been made explicit in the amended policy declaration for domestic and overseas transportation, in which Congress has not merely permitted but instructed us to place "maximum reliance on competitive market forces and on actual and potential competition" during the transition to deregulation. When this new standard is coupled with the elimination of a need to find route applications to be required by the public convenience and necessity, and the creation of what amounts to a rebuttable presumption in favor of such applications, little if anything is left of National's contention.

Certainly, the fact that the new Act continues to tie route awards to an application process, does not suggest that the Board cannot make a generic public convenience and necessity finding in support of a multiple entry policy. Even under the more rigorous language of the old Act, the mere fact that awards were geared to an application procedure did not compel the Board to define the need for a route authorization solely in terms of service by particular applicants. *C.A.B. v. State Airlines*, 338 U.S. 572 (1950). Several more recent court decisions have expressly approved generalized public convenience and necessity findings in favor of open entry into common carrier fields regulated by other agencies. *Chemical Leaman Tank Lines, Inc. v. United States*, 368 F. Supp. 925 (U.S.D.C. Del. 1973), and *Washington Utilities and Transportation Commission v. F.C.C.* 513 F.2d 1142 (9th Cir. 1975).¹⁰

⁹In the first case, the I.C.C. made a generalized public convenience and necessity finding in favor of open entry for all motor carriers interested in transporting waste commodities in furtherance of a pollution control program; in the second, a similar determination was made by the F.C.C. to let all qualified applicants into the specialized communications field. Both policy rules were adopted under statutory provisions

A second line of attack against multiple authorizations was directed at their permissive character. We responded to this legal challenge in *Las Vegas-Dallas/Fort Worth*, Order 78-7-116 pp. 11-12 and *Oakland*, Order 78-9-96, pp. 26-33. The new Act effectively moots the issue by making all authority essentially discretionary but subject to certain constraints. Specifically, it abolishes the general obligation of an airline to obtain Board permission before it can abandon service. Instead, carriers now have a broad responsibility to give notice of their intention to withdraw or, in some circumstances, reduce service, and can be required to continue operating to small communities (at consecutive 30 day intervals) whenever a cessation or reduction of service to a point would drop its overall service level below the standard of "essential air transportation," and no replacement carrier is available. If an airline is required to continue operating under this proviso, it must be compensated for any losses. Another, less significant, limitation is that dormant or under-utilized non-stop authority is smaller markets may in some instances be suspended for up to 26 weeks at a time when a "replacement" carrier enters the market under the "unused authority" program. See p. 4, note 1, above.

Such limitations on permissiveness, however, do not negate the essential

similar to old Section 401(d); both were challenged on grounds that the agency could not make a generic determination of need but was compelled instead to make individual determinations of public convenience and necessity for each applicant; and, in addition, the FCC order was attacked for not inquiring whether the service proposed by any applicant would preclude the service of any other and, if it would, for not holding comparative hearings to determine which should be selected.

Both reviewing courts rejected these arguments. (The I.C.C. waste commodities rule was remanded on other grounds but, as eventually modified, was upheld in *National Tank Truck Carriers v. I.C.C.*, 559 F.2d 845, (D.C. Cir. 1977)). *Chemical Leaman* held that the language of the Motor Carrier Act did not prescribe an exclusive format for making public convenience and necessity findings and that there was therefore no reason why the Commission could not by making "an advance classification of carriers, 'find' that the public convenience and necessity warrants operations by each carrier encompassed therein, and apply that 'finding' to those individual carriers who show they bear the common attributes of the class." 368 F. Supp. at 937. Similarly, *Washington Utilities* found that since the FCC was adopting a "general policy for uniform application in the regulation of a nationwide industry," it was proper for it to use a rulemaking approach to particularize statutory standards. Also, it concluded that the Commission had engaged in "a reasoned exercise" of its discretion in deciding not to limit entry and hold comparative hearings on issues of economic exclusivity.

⁸We cite these only as possible instances in which entry restrictions might be appropriate. We recognize that there are also significant risks in such an approach where, for example, the Board selects the wrong carrier and the net result is to delay service further or or leave the market with service inferior to what it would otherwise have been. This risk is reduced to some extent by the "unused authority" provisions of the Act which permit another carrier to "replace" a dormant incumbent.

⁹Order 78-8-97, pp. 12-18, Order 78-4-121, pp. 43-52, Order 78-9-96, pp. 5-36, Order 78-8-203, pp. 4-7 and Order 78-7-116, pp. 10-12.

freedom and flexibility that airline managements must have in making choices about what markets to enter or leave in a competitive system in which more authority is awarded than can be used at any given time.

Another aspect of the legal debate has centered on the underlying purpose of the Federal Aviation Act. Opponents have argued that a policy of multiple permissive awards would represent an abdication of the Board's regulatory responsibilities, since Congress intended to establish a fundamental scheme of controlled entry that would encourage the development of air transportation through order and financial stability and protect airlines against destructive competition and uneconomic duplication of service, including more competitive authorizations than would be warranted by demand. On the other side, the Board and proponents of freer entry have insisted that Congress established broad guidelines for determining the public convenience and necessity, guidelines that are clearly broad enough to permit us to regulate through a policy of competition, in accordance with our duty to interpret and apply general statutory principles in light of the evolving character of the industry, the changing needs of the public and knowledge gained from experience.

The purpose and legislative history of the Deregulation Act are free of such ambiguities. As noted, its purpose is to remove the primary barriers to entry into domestic and overseas air transportation in three years and to require the Board to liberalize entry during the transition—its hallmark is the belief in competition rather than concern for order and stability of a kind that understandably motivated Congress in 1938. Moreover, the Conference Committee Report (at p. 56) is explicit in saying that the new legislation gives "the C.A.B. broad discretion to establish other programs to encourage competition, such as the multiple permissive authority program established by the Board."

For all these reasons, we find that our authority to adopt a general multiple entry policy is no longer in question.

GENERAL ENVIRONMENTAL CONSIDERATIONS

While a multiple permissive licensing policy is therefore desirable from a transportation standpoint and entirely consistent with our statutory authority, its impact on the environment requires further study. We do not mean to suggest that such a policy will necessarily have a serious negative impact on the environment or on energy efficiency; quite the opposite may be true if, as is entirely possible, it does not

produce a major systemwide increase in flights but does raise load factors. Our point is only that a far-reaching change in entry policy affecting the entire nation's air transportation network should be adopted only after a careful consideration of its environmental consequences. Therefore, we have decided to issue an environmental impact statement to detail those consequences and our staff has already begun to work on the matter. We will defer any decision to adopt a general regulatory policy of essentially open entry until the environmental statement is ready. In the meantime, we will apply our general conclusions about the value of multiple permissive awards to individual cases and will consider their environmental and energy effects at the particular points and markets in issue.

TENTATIVE LAS VEGAS-DALLAS/FORT WORTH FINDINGS

The first of the six "omnibus" oral argument cases in which we are following the approach described in the previous paragraph is *Las Vegas-Dallas/Fort Worth*, probably the one most favorable on its facts to a grant of multiple permissive awards. In the next few weeks we expect to issue a decision in at least one other of the "six," as well as in other proceedings that have been deferred while we have been considering the general desirability of multiple permissive licensing. Since the new Act creates what amounts to a rebuttable presumption in favor of the grant of route applications, we will generally take up first those of the deferred cases in which no plausible argument for restraining competition can be made, except where there are affirmative reasons (such as a compelling need for service) for deciding more difficult cases rapidly.

Las Vegas-Dallas/Fort Worth is a very large market, with traffic flow that we have estimated at a minimum of 557,000 passengers in 1978; it is also primarily a vacation market and therefore particularly sensitive to the stimulation of low-fare service. By Orders 78-3-121 and 78-7-116 we decided that it needed competition (against Delta, the incumbent) and selected Braniff and Texas International Airlines to provide it. Their authority became effective on July 21, 1978. The applications of Airwest, American, Eastern and Western were deferred.

In our first round of awards in this case we recognized that the various applicants had proposed a wide range of service and price benefits and that it would be difficult to determine which carrier's combination of service and fares would be best. We initially decided on only two awards because at that stage of our evolving multiple

entry approach we were not yet prepared to license more authority than the market could reasonably be predicted to sustain. On the other hand, we concluded that the market required at least two new carriers to provide a reasonable assurance of sustained price competition. Starting from that premise, TXI and Braniff were natural choices because they were the only applicants to submit low-fare proposals into the record, thereby demonstrating "their commitment to significant price reductions from the outset of the proceeding." Order 78-7-116, p. 12.¹⁰

But now that we have decided that awards need not generally be limited to the number that a market can sustain, the advantages of letting marketplace mechanisms determine the optimal quantum and type of service for the Las Vegas-Dallas/Fort Worth route are apparent.

For example, however reasonable our earlier decision was, given its underlying premises, it would have had the effect of artificially curtailing the price/service options available to the public. By choosing only Braniff and TXI, we would be creating a lopsided service pattern in which virtually all beyond-segment service would be offered to Southeast points beyond Dallas. Extensive potential sources of feed traffic in the West, available to Airwest and Western, would remain untapped, as would a number of sizable Midwest markets that American Airlines has proposed to serve.¹¹ (Eastern, the remaining applicant, has no immediate plans to inaugurate Las Vegas-Dallas Service. Its certification, however, would clearly add to the potential competition in the market and is therefore consistent both with the underlying rationale of multiple permissive authority and the new Act's policy declaration.¹² We are not suggesting, of course, that awards to all the applicants will bring the Las Vegas-Dallas/Fort Worth market the aggregate of service and other benefits that each applicant has proposed on the assumption that it alone would be selected. That is not the point. There

¹⁰The Board also adopted the administrative law judge's conclusion that Braniff would provide more service in the primary market and benefit more beyond passengers than any other applicant, and that TXI was the carrier with the greatest need for route strengthening.

¹¹Airwest has proposed single-plane service between Dallas and Burbank, Sacramento, Spokane, Reno and Boise; Western, between Dallas and Sacramento, San Francisco, Seattle and Vancouver; and American, between Las Vegas and Cincinnati, Dayton, Indianapolis and Pittsburgh, markets in which it forecasts a total of 90,000 passengers.

¹²Eastern has submitted service proposals and a full set of exhibits; there is no question that it is a "qualified" applicant.

is simply no reason on the facts of this case for the Board to intrude on a decision-making process that is better left to the free play of competitive forces—by determining for instance, that the public should be allowed to choose only from among Las Vegas-Dallas/Southeast flights but not flights serving other regions of the country.

The public's price options would likewise be curtailed if only Braniff and TXI were licensed. We have noted that the marketplace is a more finely tuned instrument for decision-making than a Board proceeding because it responds to current circumstances (while the Board's decisional process generally relies on past facts projected to the future), and acts continuously, selecting and reselecting carriers, while the Board, once it has focused on a given market, is not likely to reexamine it for years. Order 78-7-116, p. 2. Limiting our awards to Braniff and TXI because they alone made low-fare proposals years ago when exhibits in the case were introduced, would provide a dramatic illustration of the inferiority of Board attempts to prescribe in advance the kind of service a market should have. It would deprive passengers of the opportunity to opt for low-fare packages that have since been introduced by the other applicants throughout their systems (and proposed for this particular market) or that may be introduced by them in the future in response to the changing regulatory and economic climate.¹³

Moreover, in the *Las Vegas-Dallas* case, there seems to be no affirmative reason why the Board should restrict the price/service options available to the public by engaging in carrier selection. Of all the parties, only Delta, the incumbent, and Braniff and TXI, the successful applicants have voiced any real opposition to multiple permissive awards to all remaining carriers. However, while they have had the opportunity to identify specific harmful consequences flowing from such awards, none of them has done so. Instead, they have argued that the Board cannot (or, more accurately, could not under the old Act) award more authority than it predicts a market can sustain. This contention has already been rejected. There has been no showing that multiple permissive awards would impair necessary service to the public or even result in serious harm to any carrier, although the latter consideration is not normally entitled to much weight, particularly in the competitive environment created by the Deregulation Act. Finally, we see no need to

protect TXI from further competition merely because it is a relatively small carrier. (Of course, both TXI and Braniff will in any event have received a 5-6 month head start by the time this case is completed.) As we have pointed out, the Act contemplates that the normal way to strengthen small carriers is to offer them new route opportunities rather than protection from competition. It was precisely because Congress contemplated that local service airlines like TXI would face more competition on their unsubsidized routes that it freed them (for four years) of the obligation to "share" profits in those markets with their subsidized operations. Report of the House Committee on Public Works and Transportation, p. 12. (In other words, during this period, local service carriers can keep all profits earned in non subsidized markets, and need not use some of these profits to offset losses on their subsidized systems and thereby reduce the total subsidy they receive from the Treasury).¹⁴

For all these reasons we tentatively find that the applications of Airwest, American, Eastern and Western are consistent with the public convenience and necessity and should be granted. While the parties have already had ample opportunities to comment on the general question of multiple permissive entry and, more specifically, on whether such an approach should be followed in *Las Vegas-Dallas*, we are making this finding tentative in order to permit them to address themselves to these issues in light of the new certification standards and policy declaration of the amended Act (and also to permit them to comment on our environmental and energy conclusions, below).¹⁴

DURATION OF THE AWARDS

Our awards to Braniff and TXI were for a temporary three year period due to expire July 24, 1981. Since these

¹³ We mention this only as an indication that Congress expects small carriers to face more competition under the new regulatory environment; there would be no subsidy impact on TXI in any event, since we have recently taken it off subsidy.

¹⁴ Since we are now governed by a new Act that establishes a presumption in favor of the grant of route applications, we must reject earlier arguments by some parties that we should not make multiple permissive awards here but should instead decide the case on the basis of the more restrictive assumptions under which it was originally tried. (There is no doubt, however, that multiple permissive awards are within the scope of the issues.) In view of the advanced procedural stage of the case and the length of time it has been pending, and the fact that the parties have already commented on the basic issues, the public interest clearly requires that we proceed by way of a tentative decision rather than await comments before taking a position.

carriers were being selected over other applicants because of their low-fare proposals, we found that temporary awards were necessary to provide some assurance that they would actually institute those proposals (or face the possibility of losing their authority later). But now that we have tentatively decided to license all the applicants and to let market forces establish optimal service and price levels, no purpose would be served in making the authority of Braniff, TXI or the other applicants temporary. In any case, a three-year duration would be meaningless since the new Act eliminates entry barriers at the end of 1981.

ENVIRONMENTAL AND ENERGY CONSIDERATIONS

On November 12, 1976, the Board's Bureau of Operating Rights (now part of the Bureau of Pricing and Domestic Aviation) issued a Notice of Environmental Rejection finding that any subsequent Board action in this case would not constitute a major federal action significantly affecting the environment. That finding was based on environmental evaluations, submitted by the applicants, which indicated that no applicant proposed to operate more than six daily round-trip flights between Las Vegas and Dallas/Fort Worth.

When Braniff Airways later submitted direct exhibits proposing an additional nine round trips per day, the Board issued a Second Notice of Environmental Rejection. That notice, which was issued on February 24, 1977, found that the addition of nine daily round-trips also would not constitute a major federal action significantly affecting the environment.

Both of these notices assumed that any action taken by the Board would not result in more flights being added to the market than the highest number proposed by any single applicant. They did not assume that the additional services would be provided by any particular applicant or that it would be provided by only one of the applicants.

In deciding whether to make awards to more than one of the applicants in this case, we have considered the environmental implications of multiple awards. We believe that while multiple awards are likely to encourage price competition and generate traffic they are not likely to significantly increase the number of flights operated. Rather, the lower fares resulting from increased competition will force carriers to operate with higher load factors. Thus, most, if not all, of the newly generated passengers are likely to fill seats which would otherwise have been empty.

Six carriers have applied for authority in this case. On July 21, 1977,¹⁵ we

¹⁵ Order 76-6-116.

¹³ American now offers deep-discount Super-Saver fares; Western proposes a 20 per cent across-the-board reduction in coach fares plus an off-peak fare and a one-way Super Saver fare; and Airwest proposes a broad array of promotional fares.

granted two of these applicants, Braniff and Texas International, certificates to serve the Las Vegas-Dallas/Fort Worth market. While Braniff had proposed to operate nine daily round trips and TXI proposed five, they are currently operating a total of only seven and a half daily round-trips. Thus, higher load factors and the introduction of more than one carrier into the market led both to reevaluate their proposals and provide less service than they had originally planned. We expect a similar reaction by all of the carriers when additional awards are made.

Having found that multiple awards are not likely to significantly increase the number of flights operated, we tentatively conclude that they will not have a significant impact on the environment. The Bureau's analysis showed that the level of increased service we foresee does not come close to exceeding the thresholds of our noise and pollution screening tests. Even if there is a somewhat larger increase in service, the environmental impact will not be significant.

In addition, multiple awards have favorable implications with respect to energy efficiency and consumption. The higher load factors which multiple awards are likely to induce will allow many more people to fly without significantly increasing fuel consumption or any of the other environmental consequences associated with an increase in operations. We therefore tentatively conclude that the awards we are proposing to make in this case are consistent with the National Environmental Policy Act of 1969 and the Energy Policy and Conservation Act.

Accordingly: 1. We tentatively find that (a) awards of permissive nonstop authority in the Las Vegas-Dallas/Fort Worth market to American Airlines, Eastern Airlines, Hughes Airwest and Western Air Lines are consistent with the public convenience and necessity, and that each of these carriers is fit, willing and able to operate this service; (b) the time limitation on the existing Las Vegas-Dallas/Fort Worth authority of Braniff Airways and Texas International Airlines should be removed; and (c) the proposed awards are consistent with the National Environmental Policy Act of 1969 and the Energy Policy and Conservation Act;

2. Any interested party objecting to the issuance of an order making final the tentative findings set out above, or otherwise wishing to comment on those findings, shall file its comments with the Board in Docket 29445 within 30 days of the service date of this order;

3. If no objections are filed, the Board will deem all further procedural

steps to be waived and will issue the authority described in paragraph 1;

4. If timely objections and other comments are filed, the Board will accord them full consideration before taking further action.

This order will be published in the *FEDERAL REGISTER*.

COHEN, Chairman, O'MELIA, BAILEY and SCHAFFER, Members concurred in the above opinion and order.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35675 Filed 12-21-78; 8:45 am]

[6320-01-M]

MULTIPLE PERMISSIVE AWARDS FOR ROUTE AUTHORITY

Preparation of Environmental Impact Statement

AGENCY: Civil Aeronautics Board.

ACTION: Notice of Preparation of Environmental Impact Statement.

SUMMARY: This notice announces the Board's intention to prepare an environmental impact statement assessing the effects of adopting a general policy of granting multiple permissive awards to all qualified applicants for route authority. The impact statement will cover both domestic and international authority.

DATES: Comments by January 8, 1978.

ADDRESSES: Comments should be sent to Arnold Konheim—OEA, Steven Rothenberg or Laurence J. Aurbach—BPDA, 1825 Connecticut Avenue, Washington, D.C. 20428.

FOR FURTHER INFORMATION CONTACT:

Arnold Konheim—OEA (202) 673-6089; Steven Rothenberg—OGC (202) 673-5205; or Laurence J. Aurbach—BPDA (202) 673-5449, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428.

SUPPLEMENTARY INFORMATION:

The Board is considering the adoption of a general policy of granting multiple permissive awards to all qualified applicants for domestic and overseas route authority. The Board believes that such a policy would serve the public interest by encouraging competition and increasing the incentive for carriers to provide the price and service options demanded by the public. It is commencing the preparation of an environmental impact statement to allow it to assess the environmental implications of the proposed action.

International authority will also be included in the impact statement to give the Board an overall environmental perspective of multiple entry. Although the Board is not now consider-

ing a general policy of multiple entry internationally, it may in the future. Moreover, multiple entry is and will be in issue in a number of individual international route cases before the Board.

Until now the Board has been considering the desirability of making multiple permissive awards on a case by case basis. In doing so, it has considered the environmental ramifications of each case before making any awards of certificate authority. The Board is preparing this environmental impact statement to allow it to analyze the cumulative, systemwide impacts of multiple permissive entry.

The impact statement will be used not only to allow the Board to determine whether a general policy of multiple permissive awards should be adopted but also to present it with alternatives which may be employed to minimize harmful environmental impacts associated with air transportation. The impact statement will consider both alternative policy approaches, such as making multiple awards in only certain categories of markets and combining multiple awards with a restrictive rate policy, and mitigating measures, such as requiring carriers to operate only planes meeting specified noise, air quality and/or energy criteria.

The Board will be arranging a scoping meetings with Federal agencies having jurisdiction in areas related to the proposed action and is taking this opportunity to request comments from the general public. We are especially interested in comments suggesting categories of airports which should be exempted from any general finding the Board makes and measures which might be taken to mitigate the environmental impact of multiple awards. Comments on the relationship of the proposed policy to other plans and policies are also of special interest to us.

Interested persons may participate in the preparation of this impact by submitting written data, views or arguments to the address above. Ten copies of such comments are requested but not required. All relevant material received by the date, shown at the beginning of this notice will be considered in preparing the impact statement.

Dated: December 18, 1978.

MICHAEL E. LEVINE,
*Director, Bureau of Pricing
and Domestic Aviation.*

[FR Doc. 78-35666 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Docket 30699]

OAKLAND SERVICE CASE (FITNESS PHASE)**Hearing**

Notice is hereby given, pursuant to the provisions of the Federal Aviation Act of 1958, as amended, that a public hearing in the above-entitled proceeding is assigned to be held on January 17, 1979, at 9:30 a.m. (local time) in Room 1003, Hearing Room D, Universal North Building, 1875 Connecticut Avenue N.W., Washington, D.C., before the undersigned Administrative Law Judge.

For information concerning the issues involved and other details of this proceeding, interested persons are referred to the various documents which are in the docket of this case on file in the Docket Section of the Civil Aeronautics Board.

Dated at Washington, D.C., December 15, 1978.

ARTHUR S. PRESENT,
Administrative Law Judge.

[FR Doc. 78-35668 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Order 78-12-94; Docket 32954]

TEXAS INTERNATIONAL AIRLINES, INC.**Order to Show Cause**

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 14th day of December, 1978. Application of TEXAS INTERNATIONAL AIRLINES, INC. for amendment of certificate of public convenience and necessary for Route 82.

By Order 78-10-25, October 5, 1978, we invited interested persons to show cause why we should not amend the certificate of Braniff Airways for Route 9 so as to add the point Midland/Odessa, Texas. We denied Midland's request that we authorize Braniff to provide service in the Midland/Odessa-Dallas/Ft. Worth market by exemption. Finally, we left to be handled by a later order an application of Texas International Airlines (TXI) for amendment of its certificate for Route 82 so as to provide nonstop service between Dallas/Ft. Worth and Oklahoma City.¹ The facts of that application were discussed in the order.

Braniff has responded to TXI's economic exhibits filed on August 14. It opposes the requested authority, contending that TXI is not proposing significant service improvements; that issuance of an order to show cause in response to the petition would run contrary to established Board policy be-

cause the certification sought would substantially alter existing competitive relationships in the Dallas/Ft. Worth-Oklahoma City market; and that the petition raises questions which preclude resolution by show-cause procedures.

We have tentatively concluded, on the basis of the tentative findings below, that it is consistent with the public convenience and necessity to amend TXI's certificate so as to add the nonstop segment Dallas/Ft. Worth-Oklahoma City; such service should be made permissive; TXI is fit, willing and able to perform properly the air transportation it proposes and to conform to the provisions of the Act and the Board's rules; our proposed action would not constitute a major Federal action significantly affecting the quality of the environment within the meaning of the National Environmental Policy Act of 1969; and it is not a major regulatory action under the Energy Policy and Conservation Act of 1985 (EPACA).²

Grant of TXI's request comports with the Airline Deregulation Act of 1978, particularly with the declaration of policy set forth in section 102 which instructs us to rely, to the maximum extent possible, on competitive forces, including potential competition. TXI has proposed competitive service in the primary market and service beyond Dallas/Ft. Worth to Midland/Odessa, where direct service from Oklahoma City has been eliminated by Continental. In addition, TXI has proposed fare reductions which will provide a greater choice of price. Even should TXI not enter the market, however, or ultimately leave it, the realistic threat of entry will help to force incumbents to operate efficiently and responsively.

We will give interested persons 30 days following the service date of this order to show cause why the tentative findings and conclusions set forth here should not be made final; replies will be due within 10 days thereafter. We expect those persons to direct their objections, if any, to specific matters dealt with here, and to support their objections with detailed economic analysis. If an oral evidentiary hearing complete with the opportunity for cross-examination is requested, the objector should state, in detail, why such a hearing is necessary and what relevant and material facts the objector would expect to establish through such a hearing that cannot be established in written pleadings. We will

²TXI filed an environmental evaluation, to which we received no objections, indicating that there would be no significant impact on the environment as a result of its proposed service. We have analyzed TXI's evaluation and find it to be reasonable. Its service will require the use of only 1,029,888 gallons of additional fuel.

not entertain general, vague, or unsupported objections. We remind objectors that, under the 1978 Act, the burden of proof is on them to show why the award of authority here is not consistent with the public convenience and necessity.

Accordingly, 1. We direct all interested persons to show cause why we should not issue an order making final the tentative findings and conclusions stated here and amending TXI's certificate for Route 82 by adding the segment Dallas/Ft. Worth, Tex.-Oklahoma City, Okla.;

2. We direct any interested persons having objections to the issuance of an order making final the proposed findings, conclusions and certificate amendment set forth here to file with us, no later than January 18, 1979, 1978, and serve upon all persons listed in paragraph 6 below, a statement of objections together with a summary of testimony, statistical data, and evidence expected to be relied upon to support the stated objections; interested persons shall file answers to objections no later than January 29, 1979;

3. If timely and properly supported objections are filed, we will give full consideration to the matters or issues raised before we take further action;³

4. In the event no objections are filed to any part of this order, we will eliminate all further procedural steps relating to such part or parts and we will proceed to enter an order in accordance with the tentative findings and conclusions set forth in this order;

5. We will grant the petition of Texas International Airlines for an order to show cause in Docket 32954; and

6. We will serve this order on Texas International Airlines, Inc.; Braniff Airways, Inc.; the Midland/Odessa Parties; the Texas Aeronautics Commission; Continental Air Lines, Inc.; the Dallas/Ft. Worth Parties; the City of Oklahoma City; American Airlines, Inc.; Delta Air Lines, Inc.; Trans World Airlines, Inc.; North Central Airlines, Inc.; Northwest Airlines, Inc.; and Western Air Lines, Inc.

We will publish this order in the FEDERAL REGISTER.

By the Civil Aeronautics Board: ⁴

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35674 Filed 12-21-78; 8:45 am]

¹Such authority, if granted, would permit TXI to offer Midland/Odessa-Oklahoma City one-stop service via Dallas/Ft. Worth.

³Since provision is made for the filing of objections to this order, we will not entertain petitions for reconsideration.

⁴All Members concurred.

[6320-01-M]

TRANS CONTINENTAL AIRLINES, INC.

Application for an All-Cargo Air Service Certificate

DECEMBER 15, 1978.

In accordance with Part 291 (14 CFR 291) of the Board's Economic Regulations (effective November 9, 1978), notice is hereby given that the Civil Aeronautics Board has received an application, Docket 33133, from Trans Continental Airlines, Inc., of Ypsilanti, Michigan, for an all-cargo air service certificate to provide domestic cargo transportation.

Under the provisions of § 291.12(c) of Part 291, interested persons may file an answer in opposition to this application on or before January 12, 1979. An executed original and six copies of such answer shall be addressed to the Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. It shall set forth in detail the reasons for the position taken and must relate to the fitness, willingness, or ability of the applicant to provide all-cargo air service or to comply with the Act or the Board's orders and regulations. The answer shall be served upon the applicant and state the date of such service.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35667 Filed 12-21-78; 8:45 am]

[6320-01-M]

[Order 78-12-59; Docket 30789, et al.]

TRANSATLANTIC CARGO SERVICE CASE, ET AL.

Order; Correction

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., on the 8th day of December, 1978.

In the matter of Transatlantic Cargo Service Case (Docket 30789); Applications of Saturn Airways, Inc. (Dockets 25997, 28730), Overseas National Airways, Inc. (Docket 28984), Southern Air Transport, Inc. (Docket 29332), Evergreen International Airlines, Inc. (Docket 29342), DHL Airways, Inc. (Docket 31539), Rosenbalm Aviation, Inc. (Docket 33168), Southeast Airlines, Inc. (Docket 33651), Jet Executive International, Inc. (33964), for certificates of public convenience and necessity to engage in supplemental air transportation; Application of DHL Airways, Inc. (Docket 31540) for a certificate of public convenience and necessity under section 401 of the Act; Application of DHL Corporation (Docket 31542) for approval of sections 408 and 409 relationships.

¹ See 43 FR 56801, December 15, 1978.

Ordering paragraph 6 on page 13 omitted consolidating the application of Jet Executive International, Inc., Docket 33964. Accordingly, paragraph 6 should be revised as follows:

6. We grant the petitions to consolidate the applications of Evergreen International Airlines, Inc. amendment No. 1 to Docket 29342, Southern Air Transport, Inc. amendment No. 1 to Docket 29332, Rosenbalm Aviation, Inc. in Docket 33168, Southeast Airlines, Inc. in Docket 33651, DHL Airways, Inc. and DHL Corporation in Dockets 31539 and 31540, and Jet Executive International, Inc. in Docket 33964 with Docket 30789 to the extent that each conforms to the scope of the proceeding established here;²

Dated: December 15, 1978.

PHYLLIS T. KAYLOR,
Secretary.

[FR Doc. 78-35673 Filed 12-21-78; 8:45 am]

[3510-13-M]

DEPARTMENT OF COMMERCE

National Bureau of Standards

NATIONAL BUREAU OF STANDARDS' VISITING COMMITTEE

Meeting

Pursuant to the Federal Advisory Committee Act, 5 U.S.C. App., notice is hereby given that the National Bureau of Standards' Visiting Committee will meet on Monday, February 12, 1979, from 8:00 a.m. to 4:45 p.m. and Tuesday, February 13, 1979, from 8:30 a.m. to 3:15 p.m. in Lecture Room A, Administration Building, National Bureau of Standards, Gaithersburg, Maryland.

The NBS Visiting Committee is composed of five members prominent in the fields of science and technology and appointed by the Secretary of Commerce.

The purpose of the meeting is to review the efficiency of the Bureau's scientific work and the condition of its equipment in order to assist the Committee in reporting to the Secretary of Commerce as required by law.

The public is invited to attend, and the Chairman will entertain comments or questions at an appropriate time during the meeting. Any person wishing to attend the meeting should inform Ms. Kay Byerly, Office of the Director, National Bureau of Standards, Washington, D.C. 20234, telephone 301-921-3413.

Dated: December 18, 1978.

ERNEST AMBLER,
Director.

[FR Doc. 78-35557 Filed 12-21-78; 8:45 am]

[3510-13-M]

VINYL-COVERED GLASS FIBER INSECT SCREENING AND LOUVER CLOTH

Commercial Standard; Intent To Withdraw

In accordance with § 10.12 of the Department's "Procedures for the Development of Voluntary Product Standards" (15 CFR Part 10), notice is hereby given of the intent to withdraw Commercial Standard CS 248-64, "Vinyl-Coated Glass Fiber Insect Screening and Louver Cloth."

This withdrawal action is being proposed for the reason that CS 248-64 is adequately covered by the American Society for Testing and Materials' standard ANSI/ASTM D 3656-78, "Standard Specification for Insect Screening and Louver Cloth Woven from Vinyl-Coated-Glass Fiber Yarn."

Any comments or objects concerning this intended withdrawal of this standard should be made in writing to Standards Development Services, National Bureau of Standards, Washington, D.C. 20234, on or before January 22, 1979. The effective date of withdrawal will not be less than 60 days after the final notice of withdrawal. Withdrawal action terminates the authority to refer to a published standard as a voluntary standard developed under the Department of Commerce procedures from the effective date of withdrawal.

Dated: December 18, 1978.

ERNEST AMBLER,
Director.

[FR Doc. 78-35574 Filed 12-21-78; 8:45 am]

[3510-25-M]

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

FURTHER INCREASING IMPORT RESTRAINT LEVELS FOR CERTAIN COTTON AND MAN-MADE FIBER TEXTILE PRODUCTS FROM THE REPUBLIC OF CHINA

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Increasing the levels of restraint applicable to certain cotton and man-made fiber textile products in Categories 313, 331, 338/339, 341, 347/348, 633/634/635, 641, 647, and 648, produced or manufactured in the Republic of China and exported to the United States during the agreement year which began on January 1, 1978.

(A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 4, 1978 (43 FR 884) as amended on January 25, 1978 (43 FR 342), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773) and September 5, 1978 (43 FR 39408)).

SUMMARY: Paragraph 8(a)(iii) of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of June 8, 1978, between the Governments of the United States and the Republic of China, provides that specific levels of restraint may exceed current-year limits by a designated percentage, with the amount of the carryforward used being deducted from the applicable category level in the succeeding agreement year. The Government of the Republic of China has requested application of carryforward to the current-year levels of Categories 313, 331, 338/339, 341, 347/348, 633/634/635, 641, 647, and 648.

EFFECTIVE DATE: December 18, 1978.

FOR FURTHER INFORMATION CONTACT:

Donald R. Foote, International Trade Specialist, Office of Textiles, U.S. Department of Commerce, Washington, D.C. 20230, 202-377-5423).

SUPPLEMENTARY INFORMATION: On June 16, 1978, a letter dated June 15, 1978 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs was published in the FEDERAL REGISTER (43 FR 26102), which established the levels of restraint applicable to certain specific categories of cotton, wool, and man-made fiber textile products, produced or manufactured in the Republic of China, and exported to the United States during the twelve-month period beginning on January 1, 1978 and extending through December 31, 1978. In the letter published below the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to increase the levels of restraint established for Categories 313, 331, 338/339, 341, 347/348, 633/634/635, 641, 647, and 648 to the designated amounts.

ROBERT E. SHEPHERD,
Chairman, Committee for the
Implementation of Textile
Agreements, and Deputy As-
sistant Secretary for Domestic
Business Development.

COMMITTEE FOR THE IMPLEMENTATION OF
TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
DEPARTMENT OF THE TREASURY,
WASHINGTON, D.C. 20229.

DEAR MR. COMMISSIONER: On June 15, 1978, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry for consumption, or withdrawal from warehouse for consumption, of cotton, wool and man-made fiber

textile products in certain specific categories, produced or manufactured in the Republic of China and exported to the United States during the agreement year which began on January 1, 1978, in excess of designated levels of restraint. The Chairman further advised you that the levels of restraint are subject to adjustment.¹

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on Man-Made Fiber Textile Agreement of June 8, 1978, between the Government of the United States and the Republic of China; and in accordance with the provisions of Executive Order 11651 of March 3, 1972 as amended by Executive Order 11951 of January 6, 1977, you are directed to amend, effective on December 18, 1978, the levels of restraint established in the directive of June 15, 1978, as amended, for Categories 313, 331, 338/339, 341, 347/348, 633/634/635, 641, 647, and 648 to the following levels:

Category	Amended 12-month Level of Restraint ²
313	45,472,256 Syd.
331	484,928 Doz.
338/339	498,331 Doz.
341	382,779 Doz.
347/8	845,728 Doz.
347	415,364 Doz.
348	641,796 Doz.
633/4/5	1,455,436 Doz.
633/4	959,885 Doz.
635	713,868 Doz.
641	667,774 Doz.
647	1,936,225 Doz.
648	3,261,604 Doz.

²The levels of restraint have not been adjusted to reflect any imports after December 31, 1977.

The action taken with respect to the Government of the Republic of China and with respect to imports of cotton and man-made fiber textile products from the Republic of China has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such action, fall within the foreign affairs exception to the rulemaking provisions of 5

¹The term "adjustment" refers to those provisions of the Bilateral Cotton, Wool and Man-Made Fiber Textile Agreement of June 8, 1978, between the Governments of the United States and the Republic of China which provide, in part, that: (1) within the aggregate and group limits, specific ceilings may be exceeded by designated percentages; (2) these same levels may be increased for carryforward up to 7.15 percent of the applicable Category limit; and (3) administrative arrangements or adjustments may be made to resolve minor problems arising in the implementation of the agreement.

U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ROBERT E. SHEPHERD,
Chairman, Committee for the Imple-
mentation of Textile Agreements,
and Deputy Assistant Secretary for
Domestic Business Development.

[FR Doc. 78-35628 Filed 12-21-78; 8:45 am]

[3510-25-M]

ADJUSTING IMPORT RESTRAINT LEVEL FOR CERTAIN WOOL TEXTILE PRODUCTS FROM THE SOCIALIST REPUBLIC OF ROMANIA

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: Granting an increase for carryforward in Category 443 (men's and boys' wool suits) during the agreement year which began on January 1, 1978.

(A detailed description of the categories in terms of T.S.U.S.A. numbers was published in the FEDERAL REGISTER on January 4, 1978 (43 FR 884), as amended on January 25, 1978 (43 FR 342), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773) and September 5, 1978 (43 FR 39408)).

SUMMARY: Paragraph 6(a)(ii) of the Bilateral Wool and Man-Made Fiber Textile Agreement of June 17, 1977, as amended, between the governments of the United States and the Socialist Republic of Romania provides for the borrowing of yardage from the succeeding year's levels, such amounts to be deducted from the affected category limits in the succeeding year. Pursuant to the foregoing paragraph of the bilateral agreement, the import restraint level established for Category 443 is being increased to 7,754 dozen for the twelve-month period which began on January 1, 1978 and extends through December 31, 1978, at the request of the Government of the Socialist Republic of Romania.

EFFECTIVE DATE: December 18, 1978.

FOR FURTHER INFORMATION CONTACT:

Shirley Hargrove, Trade and Industry Assistant, Office of Textiles, U.S. Department of Commerce, Washington, D.C. 20230 (202-377-5423).

SUPPLEMENTARY INFORMATION: On May 24, 1978, there was published in the FEDERAL REGISTER (43 FR 22232) a letter dated May 19, 1978 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, establishing import restraint levels for certain wool and man-made fiber textile products, produced or manufactured in the Socialist Republic of Romania, under the new textile category system, for the agreement year which began on January 1, 1978.

In the letter published below, the Chairman of the Committee for the Implementation of Textile Agreements directs the Commissioner of Customs to increase the previously established level of restraint for Category 443 to 7,754 dozen.

ROBERT E. SHEPHERD,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Domestic Business Development.

COMMITTEE FOR THE IMPLEMENTATION OF
TEXTILE AGREEMENTS

COMMISSIONER OF CUSTOMS,
Department of the Treasury,
Washington, D.C. 20229.

DEAR MR. COMMISSIONER: Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977; pursuant to the Bilateral Wool and Man-Made Fiber Textile Agreement of June 17, 1977, as amended, between the Governments of the United States and the Socialist Republic of Romania; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed to increase, effective on December 18, 1978, the twelve-month level of restraint established in the directive of May 19, 1978 for Category 443 to the following:

Category	Amended 12-Month Level of Restraint ¹
443	7,754 doz.

¹The amended level of restraint has not been adjusted to account for any entries after December 31, 1977.

The actions taken with respect to the Government of the Socialist Republic of Romania and with respect to imports of man-made fiber textile products from Romania have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the FEDERAL REGISTER.

Sincerely,

ROBERT E. SHEPHERD,
Chairman, Committee for the Implementation of Textile Agreements, and Deputy Assistant Secretary for Domestic Business Development.

[FR Doc. 78-35629 Filed 12-21-78; 8:45 am]

[6820-33-M]

COMMITTEE FOR PURCHASE FROM
THE BLIND AND OTHER SEVERELY
HANDICAPPED

IMPROVING GOVERNMENT REGULATIONS

Response to Executive Order No. 12044

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Final Notice.

SUMMARY: The Committee published on Friday, June 23, 1978 (43 FR 27229) its proposed procedures to implement Executive Order No. 12044, "Improving Government Regulations" (43 FR 12661, March 24, 1978). There were no substantive comments received as the result of that notice.

EFFECTIVE DATE: December 22, 1978.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT:

C. W. Fletcher (703) 557-1145.

The Committee for Purchase from the Blind and Other Severely Handicapped (hereafter "the Committee") adopts the following procedures for processing proposed regulations:

(a) Continue the involvement of the Executive Director in the preparation and processing of new or revised regulations;

(b) Continue the practice of obtaining approval by the Committee members of new or revised regulations;

(c) Insure that regulations are written in nontechnical language and understandable by those individuals directly concerned as well as the public;

(d) Continue to send advance copies of proposed regulations to interested parties; namely, the Federal agencies directly concerned and central non-profit agencies and to incorporate appropriate comments resulting from their review; and

(e) Allow the public at least 60 days to comment on its proposed regulations.

The Committee has no regulations which are significant under the criteria of section 2(e) of the Executive Order. There are no subject areas within the present jurisdiction of the Committee in which significant regulations under those criteria would be necessary.

The Committee has no regulations nor contemplates any regulations with major economic consequences within the meaning of section 3 of the Executive Order.

The Committee will apply the following criteria for selecting portions of its existing regulations to be reviewed:

- (a) The continued need for the particular part of the regulations;
- (b) The need to simplify and clarify the requirements; and
- (c) The type and number of complaints or suggestions received.

C. W. FLETCHER,
Executive Director.

[FR Doc. 78-35578 Filed 12-21-78; 8:45 am]

[6820-33-M]

PROCUREMENT LIST 1979

Proposed Addition

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Proposed Addition to Procurement List.

SUMMARY: The Committee has received a proposal to add to Procurement List 1979 a commodity to be produced by workshops for the blind and other severely handicapped.

COMMENTS MUST BE RECEIVED ON OR BEFORE: January 24, 1979.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 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 addition, all entities of the Federal Government will be required to procure the commodity listed below from workshops for the blind or other severely handicapped.

It is proposed to add the following commodity to Procurement List 1979, November 15, 1978 (43 FR 53151):

CLASS 8445

Scarf, Neckwear, White—8445-00-549-5363.

C. W. FLETCHER,
Executive Director.

[FR Doc. 78-35582 Filed 12-21-78; 8:45 am]

[3910-01-M]

DEPARTMENT OF DEFENSE

Department of the Air Force

USAF SCIENTIFIC ADVISORY BOARD

Meeting

DECEMBER 18, 1978.

The USAF Scientific Advisory Board Logistics Cross-Matrix Panel will hold meetings at Seymour Johnson Air Force Base, North Carolina on January 11 and 12, 1979. The meeting will convene at 8:00 a.m. and adjourn at 5:00 p.m. on January 11 and from 8:00 a.m. to 2:30 p.m. on January 12, 1979.

The Panel will receive classified briefings on the mission and functions of the two Wings' logistical support operations. The meetings will be closed to the public in accordance with Section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof.

For further information contact the Scientific Advisory Board Secretariat at (202) 697-4811.

CAROL M. ROSE,
*Air Force Federal Register
Liaison Officer.*

[FR. Doc. 78-35630 Filed 12-21-78; 8:45 am]

[3710-08-M]

Department of the Army

PRIVACY ACT OF 1974

Deletions and Addition of Record Systems

AGENCY: Department of the Army.

ACTION: Notice of Two deletions and one proposed new system of records notice under the Privacy Act.

SUMMARY: The Department of the Army proposes a new system of records identifies as A0402.01aDAJA entitled: "General Legal Files". The record system notice is published in its entirety below. This makes obsolete two system notices also identifies below.

DATES: The new system shall become effective as proposed without further notice on January 21, 1979, unless comments are received on or before January 21, 1979, which would result in a contrary determination requiring republication for further comments.

ADDRESS: Send comments to the system manager identified in the record system notice.

FOR FURTHER INFORMATION CONTACT:

Mr. Guy B. Oldaker, Administrative Management Directorate, The Adjutant General Center, Department of the Army, room GA-084, Forrestal

Building, 1000 Independence Avenue, S.W., Washington, D.C. 20314, telephone 202-693-0973.

SUPPLEMENTARY INFORMATION: The Department of the Army systems of records notices, as prescribed by the Privacy Act have been published in the FEDERAL REGISTER as follows:

FR Doc. 77-28255 (42 FR 50396) September 28, 1977

FR Doc. 78-23953 (43 FR 38070) August 25, 1978

FR Doc. 78-25562 (43 FR 40272) September 11, 1978

FR Doc. 78-26732 (43 FR 42026) September 19, 1978

FR Doc. 78-25819 (43 FR 42374) September 20, 1978

FR Doc. 78-26699 (43 FR 43059) September 22, 1978

FR Doc. 78-26996 (43 FR 43539) September 26, 1978

FR Doc. 78-29130 (43 FR 47604) October 16, 1978

FR Doc. 78-29211 (43 FR 48894) October 19, 1978

FR Doc. 78-29982 (43 FR 49557) October 24, 1978

FR Doc. 78-31795 (43 FR 52512) November 13, 1978

FR Doc. 78-34539 (43 FR 58111) December 12, 1978

Advance notice of the proposed new system of records was submitted by the Department of the Army on November 9, 1978 pursuant to the provisions of the Privacy Act of 1974 (5 U.S.C. 552a(o)).

MAURICE W. ROCHE,
*Director, Correspondence and
Directives, Washington Head-
quarters Services, Department
of Defense*

DECEMBER 18, 1978.

DELETIONS

A0402.01aDAJA

System name: Legal Opinion Precedent Files (42 FR 50463) September 28, 1977

Reason: This system is covered by the new system notice published below.

A0411.01DAJA

System name: Relief Legislative Files (42 FR 50474) September 28, 1977.

Reason: This system is covered by the new system notice published below.

ADDITION

A0402.01aDAJA

System name:

402.01 General Legal Files.

System location:

Office of The Judge Advocate General, Pentagon, Washington, D.C. 20310; Offices of Staff Judge Advocates, Judge Advocates, and Legal

Counsels of subordinate commands, installations, and organizations.

Categories of individuals covered by the system:

Individuals who have been the subject of matters (civil or criminal) referred to the Office of the Judge Advocate General or to legal offices of subordinate commands, installations, and organizations for legal opinion, legal review, or other action. Some examples of matters frequently referred for legal opinion, legal review, or other action are: Elimination and separation proceedings; questions pertaining to entitlement to pay, allowances, or other benefits; flying evaluation boards, line of duty investigations, reports of survey, and other boards of investigating officers; unfavorable information (DASEB) cases; efficiency report (DASRB) appeals; petitions to the Army Board for the correction of Military Records; matters pertaining to on-post solicitation, revocation of privileges, and bars to entry on military installations; matters pertaining to appointments, promotions, enlistments, and discharges; matters pertaining to prohibited activities and conflicts of interest for Army personnel employees; Article 138, UCMJ complaints (10 U.S.C. 938); private relief legislation; military justice matters including requests for delivery of service members for trial by civilian authorities, appeals from nonjudicial punishment imposed under Article 15 UCMJ (10 U.S.C. 815), appeals under Article 69, UCMJ 869), Secretarial review of officer dismissal cases, petitions for clemency, requests for pardons, and requests for grants of immunity for civilian witnesses; matters pertaining to civilian employees and employees of nonappropriated fund instrumentalities including employment, pay, allowances, benefits, separations, discipline and adverse actions, grievances, equal opportunity complaints, awards, and claims processed by other agencies; and correspondence addressed to the Office of The Judge Advocate General (or subordinate legal offices), or addressed to the President, members of Congress, Department of Defense, or Department of the Army which is referred to the Office of The Judge Advocate General or other legal office for response.

Categories of records in the system:

Inquiries with substantiating documents, personnel actions, investigations, petitions, complaints, or other matters to be reviewed or acted upon; legal memoranda and legal opinions; and correspondence and responses thereto. Legal opinion files which are not indexed by individual name or personal identifier are frequently com-

mingled with subject files, but are not a part of this system of records.

Authority for maintenance of the system:

Title 10 U.S.C., Sections 3037 and 3072.

Routine uses of records maintained in the system, including categories of users and the purposes of such uses:

Department of Justice for grants of immunity and requests for pardons.

Policies and practices for storing, retrieving, accessing, retaining, and disposing of records in the system:

Storage:

Paper records in file folders.

Retrievability:

Alphabetically by last name.

Safeguards:

Maintained in locked file cabinets and/or in locked offices in buildings employing security guards and/or located on military installations with military police patrols and protection.

Retention:

Permanent due to legal precedence value at Army staff and headquarters of major commands. In other offices, some types of records not having legal precedence value are retained for lesser periods (as little as two years) and destroyed.

System manager(s) and address:

The Judge Advocate General, Headquarters, Department of the Army (DAJA), Washington, D.C. 20310. For records maintained in legal offices of subordinate commands, installations, or organizations, the Staff Judge Advocate, Judge Advocate, or Chief Legal Counsel, as appropriate. Official mailing addresses are in the DOD directory in the Appendix.

Notification procedure:

Information may be obtained by writing or visiting the office of the appropriate SYSMANAGER. Written requests for notification should contain the full name, address and telephone number of the requester, and any other personal data which would assist in identifying records pertaining to the requester such as current or former military status, date of birth, SSN or service number, and if applicable, the date, place, and type of incident which the requester believes may have been referred for legal review.

Record access procedures:

Access to records may be obtained in the same manner as notification, except that requests for access in person will require verification of identity by military, civil service or de-

pendent ID card, driver's license, or other reasonable means.

Contesting record procedures:

The Army's rules for access to records and for contesting contents and appealing initial determinations are contained in AR 340-21 and 32 CFR Part 505.

Record source categories:

Legal memoranda and opinions are based on records submitted with the inquiry from various Department of the Army staff agencies, commands, installations, and organizations. When responding to correspondence, the files contain information supplied by the individual, and in some cases, facts gathered from various Department of the Army records.

Systems exempted from certain provisions of the act:

Parts of this system may be exempt under Title 5 U.S.C., Section 552a(k)(1), (2), (5), (6) or (7), as applicable. For additional information, contact the SYSMANAGER.

[FR Doc. 78-35523 Filed 12-21-78; 8:45 am]

[3810-70-M]

Office of the Secretary

DOD ADVISORY GROUP ON ELECTRON DEVICES

Meeting

Working Group D (Mainly Laser Devices) of the DOD Advisory Group on Electron Devices (AGED) will meet in closed session at the Institute for Defense Analyses, 400 Army Navy Drive, Arlington, Va. on January 18-19, 1979.

The purpose of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The laser area includes programs on developments and research related to low energy lasers for such applications as battlefield surveillance, target designation, ranging, communications, weapon guidance and data transmission. The review will include details of classified defense programs throughout.

In accordance with Section 10(d) of Appendix 1, Title 5, United States Code, it has been determined that this

Advisory Group meeting concerns matters listed in Section 552b(c) of Title 5 of the United States Code, Specifically, Subparagraph (1) thereof, and that accordingly this meeting will be closed to the public.

Dated: December 19, 1978.

MAURICE W. ROCHE,
Director, Correspondence and
Directives, Washington Head-
quarters Service, Department
of Defense.

[FR Doc. 78-35584 Filed 12-21-78; 8:45 am]

[3810-70-M]

DOD ADVISORY GROUP ON ELECTRON DEVICES

Meeting

Working Group A (Mainly Microwave Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session at 201 Varick Street, New York, N.Y. 10014, on January 18, 1979.

The purpose of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group A meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The microwave area includes programs on developments and research related to microwave tubes, solid state microwave, electronic warfare devices, millimeter wave devices, and passive devices. The review will include details of classified defense programs throughout. In accordance with Section 10(d) of Appendix 1, Title 5, United States Code, it has been determined that this meeting of the Advisory Group on Electron Devices concerns matters listed in Section 552b(c) of Title 5 of the United States Code, specifically Subparagraph (1) thereof, and that accordingly this meeting will be closed to the public.

Dated: December 19, 1978.

MAURICE W. ROCHE,
Director, Correspondence and
Directives, Washington Head-
quarters Service, Department
of Defense.

[FR Doc. 78-35584 Filed 12-21-78; 8:45 am]

[3810-70-M]**DOD ADVISORY GROUP ON ELECTRON DEVICES****Meeting**

Working Group B (Mainly Low Power Devices) of the DoD Advisory Group on Electron Devices (AGED) will meet in closed session at the Naval Air Systems Command, 1421 Jefferson Davis Highway, Arlington, Virginia 22202, on 21-22 February 1979.

The purpose of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with tactical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will be limited to review of research and development programs which the Military Departments propose to initiate with industry, universities or in their laboratories. The low power device area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with Section 10(d) of Appendix 1, Title 5, United States Code, it has been determined that this Advisory Group meeting concerns matters listed in Section 552b(c) of Title 5 of the United States Code, specifically Subparagraph (1) thereof, and that accordingly this meeting will be closed to the public.

Dated: December 19, 1978.

MAURICE W. ROCHE,
Director, Washington, Headquarters Service, Correspondence and Directives, Department of Defense.

[FR Doc. 78-35586 Filed 12-21-78; 8:45 am]

[4310-10-M]**ENDANGERED SPECIES COMMITTEE****CONSIDERATION OF AN EXEMPTION FOR THE GRAYROCKS DAM AND RESERVOIR PROJECT****Hearing**

AGENCY: Endangered Species Committee.

ACTION: Notice of Public Hearing.

SUMMARY: Public Hearings will be held on the question of whether the Grayrocks Dam and Reservoir Project on the Laramie River in Wyoming should be granted an exemption from the requirements of section 7(a) of the

Endangered Species Act of 1973, as amended.

DATES: Hearings: January 8, 1979, 9:00 A.M. Close of Record: January 10, 1979.

FOR FURTHER INFORMATION CONTACT:

Raphaelle Semmes, Room 4160, Interior Building, 18th & C Streets NW., Washington, D.C. 20240, Phone 202-343-5978.

SUPPLEMENTARY INFORMATION: The Endangered Species Act Amendments of 1978 (Amendments) create the Endangered Species Committee. The Committee is charged with the responsibility of determining whether an exemption should be granted for a particular Federal activity from the requirement of section 7(a) of the Endangered Species Act of 1973, as amended (the Act), that Federal agency actions not jeopardize the continued existence of endangered or threatened species or adversely modify their critical habitat.

The Director of the United States Fish and Wildlife Service has concluded that the Grayrocks Dam and Reservoir Project is likely to jeopardize the continued existence of the endangered whooping crane (*Grus americana*) and is likely to adversely modify its critical habitat. The Amendments direct the Endangered Species Committee to give prompt consideration to an exemption for the Grayrocks Project.

An exemption from the requirement of section 7(a) of the Act may be granted for the Grayrocks Project if: (1) There are no reasonable and prudent alternatives; and (2) the benefits of project clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and the Project is in the public interest. If an exemption is granted the Committee is directed to require such reasonable mitigation and enhancement measures as are necessary and appropriate to minimize the adverse effects of the Project.

(2) whether or not the Project is in the public interest; and

(3) appropriate reasonable mitigation and enhancement measures which should be considered by the Committee.

Any interested person who desires to present oral comments at the hearings may schedule an oral presentation in advance of the hearings by contacting by telephone either Administrative Law Judge Keith L. Burrows in Billings, Montana at 406-657-6615 or Administrative Law Judge Joseph E. McGuire in Washington, D.C. at 202-557-9200. In addition, an opportunity to schedule an oral presentation will be provided at the hearings themselves.

Interested parties are encouraged to submit written comments and statements which will also be considered, and may be submitted directly to Secretary of the Interior Cecil D. Andrus; Chairman, Endangered Species Committee; Room 4160, Interior Building; 18th and C Streets NW., Washington, D.C. 20240. Written comments may be supplemented by oral comments submitted at the hearing. All written comments and statements must be received by January 10, 1978. All written comments will be available for public inspection at Room 4153, Interior Building.

Dated: DECEMBER 20, 1978.

CECIL D. ANDRUS,
Secretary of the Interior, Chairman, Endangered Species Committee.

[FR Doc. 78-35733 Filed 12-21-78; 8:45 am]

[4310-10-M]**CONSIDERATION OF AN EXEMPTION FOR THE TELlico DAM AND RESERVOIR PROJECT****Hearing**

AGENCY: Endangered Species Committee.

ACTION: Notice of Public Hearing.

SUMMARY: Public hearings will be held on the question of whether the Tellico Dam and Reservoir Project on the Little Tennessee River in the State of Tennessee should be granted an exemption from the requirements of section 7(a) of the Endangered Species Act of 1973, as amended.

Dates: Hearings: January 8, 1979, 9:00 a.m. Close of Record: January 10, 1979.

FOR FURTHER INFORMATION CONTACT:

Raphaelle Semmes, Room 4160, Interior Building, 18th and C Streets, NW., Washington, D.C. 20240 phone: 202-343-5978.

Supplementary Information: The Endangered Species Act Amendments of 1978 (Amendments) create the Endangered Species Committee. The Committee is charged with the responsibility of determining whether an exemption should be granted for a particular Federal activity from the requirement of section 7(a) of the Endangered Species Act of 1973, as amended (the Act), that Federal agency actions not jeopardize the continued existence of endangered or threatened species or adversely modify their critical habitat.

The Director of the United States Fish and Wildlife Service has concluded that the Tellico Dam and Reservoir Project will cause the extinction of the endangered snail darter (*Percina*

tanasi) and will destroy its critical habitat. The Amendments direct the Endangered Species Committee to give prompt consideration to an exemption for the Tellico Project.

An exemption from the requirement of section 7(a) of the Act may be granted for the Tellico Project if: (1) There are no reasonable and prudent alternatives; and (2) the benefits of project clearly outweigh the benefits of alternative courses of action consistent with conserving the species or its critical habitat, and the Project is in the public interest. If an exemption is granted the Committee is directed to require such reasonable mitigation and enhancement measures as are necessary and appropriate to minimize the adverse effects of the Project.

Public hearings will be held for the purpose of receiving information and comment relevant to the Committee's determinations. The hearings will be held on January 8, 1979 in Washington, D.C. The hearings will be held at 1:00 p.m. at the Department of the Interior Auditorium, 18th and C Streets, N.W., and in Knoxville, Tennessee at 9:00 a.m. at the University of Tennessee College of Law, Moot Courtroom, 1505 West Cumberland Avenue.

Information and comment is solicited on: (1) the availability of reasonable and prudent alternatives to the Tellico Project, and the nature and extent of the benefits of the Project and of alternative courses of action which are consistent with conserving the snail darter and its critical habitat; (2) whether or not the Project is in the public interest; and (3) reasonable mitigation and enhancement measures which should be considered by the Committee.

Any interested person who desires to present oral comments at the hearings may schedule an oral presentation in advance of the hearings by contacting by telephone either Administrative Law Judge David Torbett in Knoxville, Tennessee at 615-637-8060; or Administrative Law Judge Joseph E. McGuire in Washington, D.C., at 202-557-9200. In addition, an opportunity to schedule an oral presentation will be provided at the hearings themselves.

Interested parties are encouraged to submit written comments and statements which will also be considered, and may be submitted directly to Secretary of the Interior Cecil D. Andrus, Chairman, Endangered Species Committee, Room 4160, Interior Building,

18th and C Streets, N.W., Washington, D.C. 20240. Written comments may be supplemented by oral comments submitted at the hearing. All written comments and statements must be received by January 10, 1979. All written comments will be available for public inspection at Room 4153, Interior Building, 18th and C Streets, N.W., Washington, D.C.

Dated: December 20, 1978.

CECIL D. ANDRUS,
*Secretary of the Interior, Chairman,
Endangered Species
Committee.*

[FR Doc. 78-35734 Filed 12-21-78; 8:45 am]

[6450-01-M]

DEPARTMENT OF ENERGY

Economic Regulatory Administration

CANADIAN CRUDE OIL ALLOCATION PROGRAM

Supplemental Allocation Notice for the October 1 Through December 31, 1978, Allocation Period

In accordance with § 214.32(c) of the Mandatory Canadian Crude Oil Allocation Regulations, 10 CFR Part 214, the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby issues a supplemental allocation notice to reflect a modification in the export level of Canadian light crude oil for the fourth quarter of 1978. The modification of the export level of light crude oil is due to the unavailability of Canadian condensate through Sarnia, Ontario.

The revised issuance of Canadian crude oil rights for the October 1, 1978, through December 31, 1978, allocation period to refiners and other firms is set forth in the Appendix to this notice. As to this allocation period, the Appendix lists: (1) The name of each refiner and other firm to which rights have been issued; (2) the base period volume¹ of Canadian crude oil for each refiner's first or second priority refinery; (3) the base period volume of Canadian light and heavy crude oil, respectively, for each refiner's first or second priority refinery; (4) the nominations to ERA for Canadian light and heavy crude oil, res-

spectively, of each refiner or other firm; (5) the number of rights for Canadian light and heavy crude oil, respectively, expressed in barrels per day, issued to each such refiner or other firm; and (6) the specific first or second priority refineries for which rights are applicable.

The total volume of Canadian light crude oil authorized for export to the United States, and therefore subject to allocation under Part 214, for the three month allocation period commencing October 1, 1978, will remain at the average level of 55,000 barrels per day (B/D). The export level for Canadian heavy crude oil will remain at an average of 125,315 B/D. These volumes were specified in the Allocation Notice for the current allocation period issued on September 13, 1978, (43 FR 42028, September 19, 1978).

The Canadian National Energy Board (NEB) has advised ERA that the 1,500 B/D of condensate previously available through Sarnia and allocated to Consumers Power Company at Marysville, Michigan, is not available in the fourth quarter of 1978. In order to bring the average light crude oil export volume to 55,000 B/D for this allocation period, the NEB has authorized the export of an additional 1,500 B/D of light crude oil for the fourth quarter to replace the Sarnia condensate volume. Therefore, the allocations of light crude oil to refineries receiving a fourth quarter allocation will be increased and the allocation of condensate to Consumers Power Company at Marysville, Michigan, will be eliminated. The existing operational constraint of 50 B/D of light crude oil through the Union Oil pipeline from the Reagan field in Canada to the Thunderbird refinery (second priority) at Cut Bank, Montana, continues in effect.

This notice is issued pursuant to Subpart G of ERA's regulations governing its administrative procedures and sanctions, 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 January 22, 1979.

Issued in Washington, D.C., on December 18, 1978.

DORIS DEWTON,
*Acting Assistant Administrator,
Fuels Regulation, Economic
Regulatory Administration.*

[FR Doc. 78-35543 Filed 12-21-78; 8:45 am]

¹Base period volume for the purposes of this notice means average number of barrels of Canadian crude oil included in a refinery's crude oil runs to stills or consumed or otherwise utilized by a facility other than a refinery during the base period (November 1, 1974, through October 31, 1975) on a barrels per day basis.

APPENDIX

CANADIAN ALLOCATION PROGRAM

RIGHTS - October 1, thru December 31, 1978
(Barrels Per Day)

Priority	Refiner/Refinery	Base Period Volumes			Nominations		Allocation		NOTICES
		Total Canadian Runs	Canadian Crude Oil		Light	Heavy	Light	Heavy	
			Canadian Light	Canadian Heavy					
AMOCO									
II	Whiting, Ind.	26,751	25,560	1,191	0	0	0	0	
II	Casper, Wyo.	2,991	2,991	0	0	0	0	0	
II	Mandan, N.D.	8,995	8,995	0	0	0	0	0	
II	Sugar Creek, Mo.	317	317	0	0	0	0	0	
ARCO									
II	Cherry Point, Wash.	34,225	34,225	0	0	0	0	0	
ASHLAND									
II	Buffalo, N.Y.	36,752	32,033	4,719	0	0	0	0	
II	Findlay, Ohio	2,198	33	2,165	0	0	0	0	
I	St. Paul Park, Minn.	14,707 1/	13,127 1/	1,580 1/	40,000	22,170	6,621	22,170 2/	
CLARK									
II	Blue Island, Ill.	18,764	18,764	0	0	0	0	0	
CONSUMERS POWER									
I	Essexville, Mich.	13,872	13,872	0	0	0	0	0	
I	Marysville, Mich.	27,306	27,306	0	1,500	0	0	0	
CONTINENTAL									
I	Billings, Mont.	25,994	25,994	0	25,994	0	13,111	0	
II	Denver, Colo.	4,639	4,639	0	4,638	0	0	0	
II	Ponca City, Ok.	1,188	1,188	0	1,188	0	0	0	
I	Wrenshall, Minn.	20,651	20,651	0	20,651	0	10,416	0	
CRA									
II	Coffeyville, Kan.	318	318	0	0	0	0	0	
II	Phillipsburg, Kan.	173	173	0	0	0	0	0	
II	Scottsbluff, Neb.	401	401	0	0	0	0	0	

Priority	Refiner/Refinery	Base Period Volumes			Nominations		Allocation	
		Total Canadian Runs	Canadian Light Crude Oil	Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy
II	CRYSTAL Carson City, Mich.	1,104	1,104	0	0	0	0	0
II	DOW CHEMICAL, U.S.A. Bay City, Mich.	2,767	2,767	0	0	0	0	0
II	ENERGY COOPERATIVE East Chicago, Ind.	10,804	10,267	537	0	0	0	0
I	EXXON Billings, Mont.	15,908	15,908	0	16,000	0	8,024	0
I	FARMERS UNION Laurel, Mont.	13,439	13,439	0	13,500	0	6,778	0
II	GLADIEUX Fort Wayne, Ind.	774	774	0	0	0	0	0
II	GULF Toledo, Ohio	13,253	13,253	0	0	0	0	0
II	HUSKY Cheyenne, Wyo. Cody, Wyo.	4,865 806	4,865 806	0 0	0 0	0 0	0 0	0 0
I	KOCH Pine Bend, Minn.	44,383 1/	3,396 1/	40,987 1/	0	95,000	0	74,383 2/
I	LAKE SUPERIOR D.P. Ashland, Wisc.	125	125	0	0	0	0	0
II	LAKESIDE Kalamazoo, Mich.	1,240	1,240	0	0	0	0	0
II	LAKETON Laketon, Ind.	141	10	131	0	0	0	0
II	LITTLE AMERICA Casper, Wyo. Sinclair, Wyo.	2,248 709	2,248 709	0 0	0 0	0 0	0 0	0 0

Priority	Refiner/Refinery	Base Period Volumes			Nominations		Allocation	
		Total Canadian Runs	Canadian Light Crude Oil	Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy
II	MARATHON Detroit, Mich.	10,301	10,159	142	19,022	0	0	0
II	MOBIL Buffalo, N.Y.	24,995	24,995	0	0	4,314	0	0
II	Ferndale, Wash.	45,444	45,444	0	0	7,844	0	0
II	Joliet, Ill.	14,606	2,132	12,474	0	12,842	0	12,202
I	MURPHY Superior, Wisc.	25,625	20,253	5,372	10,000	10,000	10,000	10,000
II	NCRA McPherson, Kan.	836	836	0	0	0	0	0
II	PESTER REFINING CO. El Dorado, Kan.	196	196	0	0	0	0	0
II	PHILLIPS Great Falls, Mont.	1,222	1,222	0	0	0	0	0
II	Kansas City, Kan.	3,352	3,105	247	0	0	0	0
II	ROCK ISLAND Indianapolis, Ind.	1,063	1,063	0	0	0	0	0
II	SHELL Anacortes, Wash.	55,919	55,919	0	0	0	0	0
II	Wood River, Ill.	8,673	8,673	0	0	0	0	0
II	SOHIO Toledo, Ohio	29,182	29,182	0	0	0	0	0
II	SUN Toledo, Ohio	16,427	16,427	0	0	0	0	0
II	TENNECO Chalmette, La.	1,767	1,767	0	0	0	0	0

Priority	Refiner/Refinery	Base Period Volumes			Nominations			Allocation	
		Total Canadian Runs	Canadian Light Crude Oil	Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy	
	TEXACO								
II	Anacortes, Wash.	41,229	41,229	0	0	0	0	0	0
II	Casper, Wyo.	1,380	1,380	0	0	0	0	0	0
II	Lockport, Ill.	1,244	1,244	0	0	0	0	0	0
	TEXAS AMERICAN								
II	West Branch, Mich.	2,011	2,011	0	0	0	0	0	0
	THE REFINERY CORP.								
II	Commerce City, Colo.	174	174	0	0	0	0	0	0
	THUNDERBIRD								
II	Cut Bank, Mont.	554	554	0	50	0	3/ 50	0	0
	TOTAL PETROLEUM								
II	Alma, Mich.	9,727	3,020	6,707	0	8,000	0	6,560	0
	UNION OIL OF CALIF.								
II	Lemont, Ill.	11,711	11,711	0	10,000	20,000	0	0	0
	UNITED REFINING								
II	Warren, Pa.	9,917	9,789	128	0	0	0	0	0
	WYOMING REFINING CO.								
II	New Castle, Wyo.	676	676	0	0	0	0	0	0
	TOTAL PRIORITY I	202,010	154,071	47,939	127,645	127,170	54,950	106,553	0
	TOTAL PRIORITY II	469,029	440,588	28,441	34,898	53,000	50	18,762	0
	TOTAL I&II	671,039	594,659	76,380	162,543	180,170	55,000	125,315	0

- 1/ Adjusted.
 2/ Adjustments to base period volumes not given effect in allocation of Canadian heavy crude oil.
 3/ Operational constraint.

[6450-01-M]

CANADIAN CRUDE OIL ALLOCATION
PROGRAMAllocation Notice for the January 1 Through
March 31, 1979, Allocation Period

In accordance with the provisions of the Mandatory Canadian Crude Oil Allocation Regulations, 10 CFR Part 214, the Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby publishes the allocation notice specified in § 214.32 for the allocation period commencing January 1, 1979.

The issuance of Canadian crude oil rights for the January 1, 1979, allocation period to refiners and other firms is set forth in the Appendix to this notice. As to this allocation period, the Appendix lists: (1) The name of each refiner and other firm to which rights have been issued; (2) the base period volume¹ of Canadian crude oil for each first or second priority refinery; (3) the base period volume of Canadian light and heavy crude oil, respectively, for each first or second priority refinery; (4) the nominations to ERA for Canadian light and heavy crude oil, respectively, of each refiner or other firm; (5) the number of rights for Canadian light and heavy crude oil, respectively, expressed in barrels per day, issued to each such refiner or other firm; and (6) the specific first or second priority refineries for which rights are applicable.

The issuance of Canadian crude oil rights is made pursuant to § 214.31, which provides that rights may be issued to refiners or other firms that own or control a first or second priority refinery based on the number of barrels of Canadian light and heavy crude oil, respectively, included in the refinery's volume of crude oil runs to stills or consumed or otherwise utilized by a facility other than a refinery during the base period, November 1, 1974, through October 31, 1975. These calculations have been made and are shown on a barrels per day basis.

The listing contained in the Appendix also reflects any adjustments made by ERA to base period volumes to compensate for reductions in volumes due to unusual or nonrecurring operating conditions or to reflect current operating conditions as provided by § 214.31(d).

Based on its review of the affidavits, supplemental affidavits and reports

¹Base period volume for the purposes of this notice means average number of barrels of Canadian crude oil included in a refinery's crude oil runs to stills or consumed or otherwise utilized by a facility other than a refinery during the base period (November 1, 1974, through October 31, 1975) on a barrels per day basis.

filed pursuant to Subpart D of Part 214, and other information available to the agency, ERA has designated each refinery or other facility listed in the Appendix as a first or second priority refinery as defined in § 214.21. If a refinery or other facility has not been designated as a priority refinery by ERA, such refinery or other facility is not entitled to process or otherwise consume Canadian crude oil subject to allocation under the program.

As provided by § 214.31(e), in the allocation period commencing January 1, 1979, each refinery or other firm which has been issued Canadian crude oil rights for light and heavy crude oil, respectively, is entitled to process, consume or otherwise utilize in the priority refinery or refineries specified in the Appendix to this notice a number of barrels of Canadian light and heavy crude oil, respectively, subject to allocation under Part 214, equal to the number of rights specified in the Appendix.

The Canadian National Energy Board (NEB) has advised ERA that the total volumes of Canadian light and heavy crude oil authorized for export to the United States, and therefore subject to allocation under Part 214, for the three-month allocation period commencing January 1, 1979, will be as follows: The average export level for Canadian light crude oil will be 55,062 barrels per day (B/D) for January, February, and March. The average export level for Canadian heavy crude oil will be 154,480 B/D for January, 152,278 B/D for February, and 151,019 B/D for March. For purposes of determining allocations of Canadian heavy crude oil, it has been assumed that the average export level will be 152,603 B/D for the three months. Any change in the export levels for Canadian light crude oil, including condensate, and Canadian heavy crude oil anticipated for this allocation period will be reflected in revised allocations that will be issued in a supplemental allocation notice or notices.

The NEB has formally advised ERA of the following operational constraint with respect to the export of Canadian light crude oil for the allocation period:

50 B/D of light crude oil through the Union Oil pipeline from the Reagan field in Canada to the Thunderbird refinery (second priority) at Cut Bank, Montana.

ERA has given effect to this operational constraint in the allocations set forth in the Appendix.

ALLOCATION OF CANADIAN LIGHT CRUDE
OIL

The authorized export level for Canadian light crude oil for this allocation period is 55,062 B/D. The adjusted base period volumes of Canadian

light crude oil for all first priority refineries nominating for light crude oil substantially exceeds the light crude oil export level. Accordingly, with the exception of allocations of light crude oil required by the operational constraint, no allocations of light crude oil are shown for second priority refineries. The export level of light crude oil, as adjusted to reflect the operational constraint, was allocated among first priority refineries nominating for light crude oil on a pro rata basis in the following manner. First, an allocation factor of 0.402493² was applied to each first priority refinery's adjusted base period volume of light crude oil. Second, the resulting allocation for Consumers Power Company was reduced to conform to their nomination for light crude oil for their Marysville first priority facility. Third, the allocation factor was recomputed as 0.492009³ to reflect this adjustment and was reapplied to each first priority refinery's (excluding Consumers Power's Marysville facility) adjusted base period volume of light crude oil to arrive at the final allocations.

ALLOCATION OF CANADIAN HEAVY CRUDE
OIL

The authorized export level for Canadian heavy crude oil for January, February, and March 1979, is an average of 152,603 B/D. Allocations of heavy crude oil were made as follows, according to the six steps specified in § 214.31(a)(3).

First, the first priority refineries for which nominations had been submitted were allocated heavy crude oil equal to one-fourth of their total base period volumes of Canadian heavy crude oil. Second, the first priority refineries for which nominations had been submitted were allocated heavy crude oil equal to one-fourth of their total base period volumes less oil already allocated to them. The nominations of two of the refineries (Murphy-Superior, Wis. and Ashland-St. Paul Park, Minn.) were less than their remaining base period volumes and they were therefore given allocations equal to their nominations. Third, second priority refineries with base period Canadian heavy crude oil runs to stills were allocated heavy crude oil equal to one-fourth of their base period Canadian

²0.402493=Adjusted export level for Canadian light crude oil (55,062 B/D less 50 B/D to Thunderbird refinery=55,012 B/D), divided by sum of adjusted base period volumes of Canadian light crude oil for first priority refineries nominating for Canadian light crude oil (136,678 B/D).

³0.492009=Adjusted export level for light crude oil (55,012 B/D, less allocation to Consumers Power Marysville facility (1,200 B/D)=53,812 B/D), divided by sum of first priority refineries' (excluding Consumers Power) adjusted base period volumes of light crude oil (109,372 B/D).

dian heavy crude oil runs to stills. Fourth, one first priority refiner submitted nominations for more Canadian crude oil than its refinery processed during the base period (Koch-Pine Bend, Minn.) and it was allocated heavy crude oil equal to its nomination. Fifth, the remainder of the Canadian heavy crude oil exports were allocated to second priority refineries on a pro-rata basis not to exceed one-fourth of their total base period volumes of Canadian crude oil less crude oil allocated under the four preceding steps and not to exceed their nominations. This step went through several iterations. Allocations under the sixth step (allocations on a pro rata basis up to but not to exceed nominations or capacities of second priority refineries, whichever are less) were not necessary because there was not enough heavy crude oil to cover the total Canadian base period volumes for all refineries for which nominations had been received.

On or prior to the thirtieth day preceding each allocation period, each refiner or other firm that owns or controls a first priority refinery shall file with ERA the supplemental affidavit specified in § 214.41(b) to confirm the continued validity of the statements and representations contained in the previously filed affidavit or affidavits, upon which the designation for that priority refinery is based. Each refiner or other firm owning or controlling a first or second priority refinery shall

also file the periodic report specified in § 214.41(d)(1) on or prior to the thirtieth day preceding each allocation period, provided, however, that the information as to estimated nominations specified in § 214.41(d)(1)(i) is not required to be reported.

Within 30 days following the close of each three-month allocation period, each refiner or other firm that owns or controls a priority refinery shall file the periodic report specified in § 214.41(d)(2) certifying the actual volumes of Canadian crude oil and Canadian plant condensate included in the crude oil runs to stills of or consumed or otherwise utilized by each such priority refinery (specifying the portion thereof that was allocated under Part 214) for the allocation period.

This notice is issued pursuant to Subpart G of ERA's regulations governing its administrative procedures and sanctions, 10 CFR Part 205. Any person aggrieved hereby may file an appeal with DOE's Office of Hearings and Appeals in accordance with Subpart H of 10 CFR Part 205. Any such appeal shall be filed on or before 30 days from the publication of this Notice.

Issued in Washington, D.C. on December 18, 1978.

DORIS DEWTON,
*Acting Assistant Administrator,
Fuels Regulation, Economic
Regulatory Administration.*

[FR Doc. 78-35544 Filed 12-21-78; 8:45 am]

APPENDIX

CANADIAN ALLOCATION PROGRAM

RIGHTS - January 1, thru March 31, 1979
(Barrels Per Day)

Priority	Refiner/Refinery	Base Period Volumes				Nominations		Allocation	
		Total Canadian Runs	Canadian		Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy
			Light Crude Oil	Crude Oil					
AMOCO									
II	Whiting, Ind.	26,751	25,560	1,191	0	0	0	0	0
II	Casper, Wyo.	2,991	2,991	0	0	0	0	0	0
II	Mandan, N.D.	8,995	8,995	0	0	0	0	0	0
II	Sugar Creek, Mo.	317	317	0	0	0	0	0	0
ARCO									
II	Cherry Point, Wash.	34,225	34,225	0	0	0	0	0	0
ASHLAND									
II	Buffalo, N.Y.	36,752	32,033	4,719	0	0	0	0	0
II	Findlay, Ohio	2,198	33	2,165	0	0	0	0	0
I	St. Paul Park, Minn.	14,707 1/	13,127 1/	1,580 1/	40,000	9,000	6,459	9,000 2/	2/
CLARK									
II	Blue Island, Ill.	18,764	18,764	0	0	0	0	0	0
CONSUMERS POWER									
I	Essexville, Mich.	13,872	13,872	0	0	0	0	0	0
I	Marysville, Mich.	27,306	27,306	0	1,200	0	1,200	0	0
CONTINENTAL									
I	Billings, Mont.	25,994	25,994	0	25,994	0	12,789	0	0
II	Denver, Colo.	4,639	4,639	0	4,638	0	0	0	0
II	Ponca City, Ok.	1,188	1,188	0	1,188	0	0	0	0
I	Wrenshall, Minn.	20,651	20,651	0	20,651	0	10,160	0	0
CRA									
II	Coffeyville, Kan.	318	318	0	0	0	0	0	0
II	Phillipsburg, Kan.	173	173	0	0	0	0	0	0
II	Scottsbluff, Neb.	401	401	0	0	0	0	0	0

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Priority	Refiner/Refinery	Base Period Volumes			Nominations		Allocation	
		Total Canadian Runs	Canadian Light Crude Oil	Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy
II	CRYSTAL Carson City, Mich.	1,104	1,104	0	0	0	0	0
II	DOW CHEMICAL, U.S.A. Bay City, Mich.	2,767	2,767	0	0	0	0	0
II	ENERGY COOPERATIVE East Chicago, Ind.	10,804	10,267	537	0	0	0	0
I	EXXON Billings, Mont.	15,908	15,908	0	16,000	0	7,827	0
I	FARMERS UNION Laurel, Mont.	13,439	13,439	0	13,500	0	6,612	0
II	GLADIEUX Fort Wayne, Ind.	774	774	0	0	0	0	0
II	GULF Toledo, Ohio	13,253	13,253	0	0	0	0	0
II	HUSKY Cheyenne, Wyo. Cody, Wyo.	4,865 806	4,865 806	0 0	0 0	0 0	0 0	0 0
I	KOCH Pine Bend, Minn.	44,383 1/	3,396 1/	40,987 1/	0	95,000	0	95,000 2/
I	LAKE SUPERIOR D.P. Ashland, Wisc.	125	125	0	0	0	0	0
II	LAKESIDE Kalamazoo, Mich.	1,240	1,240	0	0	0	0	0
II	LAKETON Laketon, Ind.	141	10	131	0	0	0	0
II	LITTLE AMERICA Casper, Wyo. Sinclair, Wyo.	2,248 709	2,248 709	0 0	0 0	0 0	0 0	0 0

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Priority	Refiner/Refinery	Base Period Volumes				Nominations			Allocation	
		Total Canadian Runs	Canadian		Canadian Heavy Crude Oil	Light	Heavy		Light	Heavy
			Light	Crude Oil						
II	MARATHON Detroit, Mich.	10,301	10,159		142		26,000	0	0	0
II	MOBIL Buffalo, N.Y.	24,995	24,995		0	0	0	870	0	870
II	Ferndale, Wash.	45,444	45,444		0	0	0	1,582	0	1,582
II	Joliet, Ill.	14,606	2,132		12,474	0	0	12,548	0	12,548
I	MURPHY Superior, Wisc.	25,625	20,253		5,372		10,000	9,000	9,965	9,000
II	NCRA McPherson, Kan.	836	836		0	0	0	0	0	0
II	PESTER REFINING CO. El Dorado, Kan.	196	196		0	0	0	0	0	0
II	PHILLIPS Great Falls, Mont.	1,222	1,222		0	0	0	0	0	0
II	Kansas City, Kan.	3,352	3,105		247	0	0	0	0	0
II	ROCK ISLAND Indianapolis, Ind.	1,063	1,063		0	0	0	0	0	0
II	SHELL Anacortes, Wash.	55,919	55,919		0	0	0	0	0	0
II	Wood River, Ill.	8,673	8,673		0	0	0	0	0	0
II	SOHIO Toledo, Ohio	29,182	29,182		0	15,000	10,000	0	0	10,000
II	SUN Toledo, Ohio	16,427	16,427		0	0	0	0	0	0
II	TENNECO Chalmette, La.	1,767	1,767		0	0	0	0	0	0

Priority	Refiner/Refinery	Base Period Volumes			Nominations				Allocation	
		Total Canadian Runs	Canadian Light Crude Oil	Canadian Heavy Crude Oil	Light	Heavy	Light	Heavy	Light	Heavy
II	TEXACO									
II	Anacortes, Wash.	41,229	41,229	0	0	0	0	0	0	0
II	Casper, Wyo.	1,380	1,380	0	0	0	0	0	0	0
II	Lockport, Ill.	1,244	1,244	0	0	0	0	0	0	0
II	TEXAS AMERICAN									
II	West Branch, Mich.	2,011	2,011	0	0	0	0	0	0	0
II	THE REFINERY CORP.									
II	Commerce City, Colo.	174	174	0	0	0	0	0	0	0
II	THUNDERBIRD									
II	Cut Bank, Mont.	554	554	0	50	0	3/50	0	0	0
II	TOTAL PETROLEUM									
II	Alma, Mich.	9,727	3,020	6,707	0	8,000	0	0	8,000	0
II	UNION OIL OF CALIF.									
II	Lemont, Ill.	11,711	11,711	0	10,000	20,000	0	0	6,603	0
II	UNITED REFINING									
II	Warren, Pa.	9,917	9,789	128	0	0	0	0	0	0
II	WYOMING REFINING CO.									
II	New Castle, Wyo.	676	676	0	0	0	0	0	0	0
II	TOTAL PRIORITY I	202,010	154,071	47,939	127,345	113,000	55,012	113,000	55,012	113,000
II	TOTAL PRIORITY II	469,029	440,588	28,441	56,876	53,000	50	39,603	50	39,603
II	TOTAL I&II	671,039	594,659	76,380	184,221	166,000	55,062	152,603	55,062	152,603

1/ Adjusted.

2/ Adjustments to base period volumes not given effect in allocation of Canadian heavy crude oil.

3/ Operational constraint.

[6450-01-M]

[Docket No. ERA-R-78-25]

REQUIREMENT FOR STATE AND LOCAL AGENCIES TO NOTIFY THE DEPARTMENT OF ENERGY OF THEIR RATEMAKING AUTHORITY OVER GAS AND ELECTRIC UTILITIES COVERED BY TITLES I AND III OF THE PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978 AND TITLE II OF THE NATIONAL ENERGY CONSERVATION POLICY ACT OF 1978

AGENCY: Economic Regulatory Administration (ERA), Department of Energy (DOE).

ACTION: Notice.

SUMMARY: Sections 102(c) and 301(d) of the Public Utility Regulatory Policies Act (PURPA) (Pub. L. 95-617) and section 211(b) of the National Energy Conservation Policy Act (NECPA) (Pub. L. 95-619) require the Secretary of Energy to publish lists, before the beginning of each calendar year, identifying each gas utility and electric utility to which Titles I and III of PURPA and Part 1 of Title II of NECPA, apply during such calendar year. This Notice includes the list for 1979 and requires each State regulatory authority to notify the Secretary of Energy of each gas and electric utility on the list for which such State regulatory authority has ratemaking authority. This Notice also requests public comment on the accuracy of the list of gas utilities and electric utilities.

DATE: State regulatory authorities must respond in writing on or before January 29, 1979. Other written comments on the accuracy of the lists should also be received by January 29, 1979.

ADDRESS: State regulatory authorities must send 15 copies of the required written response to: Department of Energy, Office of Public Hearing Management, Room 2313, 2000 M Street, NW., Docket No. ERA-R-78-25, Washington, D.C. 20461, Telephone: (202) 254-5201.

Other persons or organizations wishing to comment on the accuracy of the lists should send 5 copies of written comments to the address above.

Letters should include the writer's name, address and telephone number.

FOR FURTHER INFORMATION CONTACT:

Jeffrey A. Serfass, Office of Utility Systems Economic Regulatory Administration, Department of Energy, 2000 M Street, NW. (Vanguard 538), Washington, D.C. 20461, Telephone: (202) 254-9700.

NOTICE

As required by the Public Utility Regulatory Policies Act (PURPA), sections 102(c) and 301(d), and the National Energy Conservation Policy Act (NECPA), section 211(b), hereinafter referred to as the "Act(s)", the U.S. Department of Energy (DOE) is publishing the following list of utilities which sell natural gas and electricity and will be covered by the Act(s) in 1979. As further required by the Act(s), State regulatory authorities are to notify the Secretary of Energy as to their ratemaking authority over listed utilities. One of the chief purposes of this Notice is to inform utilities, other government agencies, and interested persons as to which utilities are covered by the two Act(s). The inclusion or exclusion of any utility does not affect the legal obligations of such utility or the responsible State regulatory authority under the Act(s).

The term "State regulatory authority" means any agency of the 50 States, the District of Columbia or Puerto Rico (or political subdivision thereof), which has authority to fix, modify, or approve rates for the sale of electric energy or natural gas by any utility (other than by such State agency), except that in the case of a utility for which the Tennessee Valley Authority (TVA) has ratemaking authority, the term "State regulatory authority" means the TVA.

Title I of PURPA (Pub. L. 95-617) deals with retail regulatory policies for electric utilities. Section 102(c) requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each electric utility to which Title I applies during such calendar year. An electric utility is defined as any person, State agency or Federal agency, which sells electric energy. An electric utility is covered by Title I for any calendar year if the electric utility had total sales of electric energy for purposes other than resale in excess of 500 million kilowatt-hours during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. An electric utility is covered in 1979 if it exceeded the threshold in 1976 or 1977.

Title III of PURPA deals with retail policies for natural gas utilities. Section 301(d) of Title III requires the Secretary of Energy to publish a list, before the beginning of each calendar year, identifying each gas utility to which Title III applies during such calendar year. A gas utility is defined as any person, State agency or Federal agency, engaged in the local distribution and the sale of natural gas to any ultimate consumer of natural gas. A gas utility is covered by Title III for any calendar year if the gas utility had total sales of natural gas for pur-

poses other than resale in excess of 10 billion cubic feet during any calendar year beginning after December 31, 1975, and before the immediately preceding calendar year. A gas utility is covered in 1979 if it exceeded the threshold in 1976 or 1977.

Title II, Part 1, of NECPA (Pub. L. 95-619) deals with residential conservation programs. Section 211(b) also contains a requirement to publish a list of electric and gas utilities. The NECPA requirements for coverage of gas utilities and electric utilities are different in three respects:

(1) The threshold for electric utilities is 750 million kilowatt-hours for purposes other than resale;

(2) A utility is covered for any calendar year if it exceeded the threshold during the second preceding calendar year. A utility is covered in 1979 if it exceeded the threshold in 1977; and

(3) Only utilities which have some residential sales are covered.

The following list covers both PURPA and NECPA requirements, with exceptions noted for listed utilities not covered by NECPA. The list is alphabetical, but subdivided into electric utilities and gas utilities and further subdivided by type of ownership: privately-owned, publicly-owned, and rural cooperative.

All electric utilities, except those marked (*), are covered by both the regulatory policy provisions of PURPA Title I and the residential conservation provisions of NECPA. All gas utilities, except those marked (*), are covered by both the regulatory policy provisions of PURPA Title III, and the residential conservation provisions of NECPA. Those electric utilities marked (8) are not covered by NECPA.

No later than January 29, 1979, each State regulatory authority must notify the Department of Energy of each utility on the list over which it has ratemaking authority. Such notification must include appropriate legal citations, and for any listed utility known to be subject to other rate-making authorities within the State for other portions of its service area, a precise description of the portion to which such notification applies. In the event that more than one agency claims ratemaking authority over the same service area of any listed utility, the Secretary will request such agencies to identify the lead agency for purposes of PURPA and NECPA compliance, reporting, and eligibility for financial assistance.

All interested persons including State regulatory authorities, are invited to comment on any errors or omissions with respect to the list.

ELECTIC UTILITIES

All utilities listed below had electric energy sales, for purposes other than resale, in excess of 500 million kilowatt-hours in 1976 or 1977. All, except those marked (*), are covered by PURPA Title I and NECPA Title II. Utilities marked (*) either do not exceed the NECPA threshold of 750 million kilowatt-hours in 1977 or do not have residential sales and, therefore, they are not covered by NECPA Title II.

INVESTOR-OWNED

Alabama Power Company
 *Alcoa Generating Corporation
 Appalachian Power Company
 Arizona Public Service Company
 Arkansas-Missouri Power Company
 Arkansas Power & Light Company
 Atlantic City Electric Company
 Baltimore Gas & Electric Company
 Bangor Hydro-Electric Company
 Black Hills Power & Light Company
 Blackstone Valley Electric Company
 Boston Edison Company
 Brockton Edison Company
 California-Pacific Utilities Company
 Cambridge Electric Light Company
 Carolina Power & Light Company
 Central Hudson Gas & Electric Corporation
 Central Illinois Light Company
 Central Illinois Public Service Company
 Central Louisiana Electric Company
 Central Maine Power Company
 Central Power & Light Company
 Central Telephone & Utilities Corporation
 Central Vermont Public Service Corporation
 Cincinnati Gas & Electric Company
 Citizens Utilities Company
 Cleveland Electric Illuminating Company
 Columbus & Southern Ohio Electric Company
 Commonwealth Edison Company
 Community Public Service Company
 Connecticut Light & Power Company
 Consolidated Edison Company of New York
 Consumers Power Company
 Dallas Power & Light Company
 Dayton Power & Light Company
 Delmarva Power & Light Company
 Detroit Edison Company
 Duke Power Company
 Duquesne Light Company
 El Paso Electric Company
 Electric Energy, Incorporated
 Empire District Electric Company
 *Fall River Electric Light Company
 Florida Power Corporation
 Florida Power & Light Company
 Georgia Power Company
 Green Mountain Power Corporation
 Gulf Power Company
 Gulf States Utilities Company
 Hartford Electric Light Company
 Hawaiian Electric Company
 Houston Lighting & Power Company
 Idaho Power Company
 Illinois Power Company
 *Indiana & Michigan Electric Company
 Indianapolis Power & Light Company
 Interstate Power Company
 Iowa Electric Light & Power Company
 Iowa-Illinois Gas & Electric Company
 Iowa Power & Light Company
 Iowa Public Service Company
 Iowa Southern Utilities Company
 Jersey Central Power & Light Company

Kansas City Power & Light Company
 Kansas Gas & Electric Company
 Kansas Power & Light Company
 Kentucky Power Company
 Kentucky Utilities Company
 Kingsport Power Company
 *Lake Superior District Power Company
 Long Island Lighting Company
 Louisiana Power & Light Company
 Louisville Gas & Electric Company
 Madison Gas & Electric Company
 Massachusetts Electric Company
 Metropolitan Edison Company
 Minnesota Power & Light Company
 Mississippi Power Company
 Mississippi Power & Light Company
 *Missouri Edison Company
 Missouri Power & Light Company
 Missouri Public Service Company
 Missouri Utilities Company
 Monongahela Power Company
 Montana-Dakota Utilities Company
 Montana Power Company
 Narragansett Electric Company
 Nevada Power Company
 New Bedford Gas & Edison Light Company
 *New Mexico Electric Service Company
 New Orleans Public Service
 New York State Electric & Gas Corporation
 Niagara Mohawk Power Corporation
 Northern Indiana Public Service Company
 Northern States Power Company
 *Northwestern Public Service Company
 Ohio Edison Company
 Ohio Power Company
 Ohio Valley Electric Corporation
 Oklahoma Gas & Electric Company
 *Old Dominion Power Company
 Orange & Rockland Utilities
 Otter Tail Power Company
 Pacific Gas & Electric Company
 Pacific Power & Light Company
 Pennsylvania Electric Company
 Pennsylvania Power & Light Company
 Pennsylvania Power Company
 Philadelphia Electric Company
 Portland General Electric Company
 Potomac Edison Company
 Potomac Electric Power Company
 Public Service Company of Colorado
 Public Service Company of Indiana
 Public Service Company of New Hampshire
 Public Service Company of New Mexico
 Public Service Company of Oklahoma
 Public Service Electric & Gas Company
 Puget Sound Power & Light Company
 Rochester Gas & Electric Corporation
 Rockland Electric Company
 St. Joseph Light & Power Company
 San Diego Gas & Electric Company
 Savannah Electric & Power Company
 Sierra Pacific Power Company
 South Carolina Electric & Gas Company
 Southern California Edison Company
 Southern Indiana Gas & Electric Company
 Southwestern Electric Power Company
 *Southwestern Electric Service Company
 Southwestern Public Service Company
 Tampa Electric Company
 Texas Electric Service Company
 Texas Power & Light Company
 Toledo Edison Company
 Tucson Gas & Electric Company
 *UGI Corporation
 Union Electric Company
 Union Light, Heat & Power Company
 United Illuminating Company
 *Upper Peninsula Power Company
 Utah Power & Light Company
 Virginia Electric & Power Company
 Washington Water Power Company
 West Penn Power Company

West Texas Utilities Company
 Western Massachusetts Electric Company
 Wheeling Electric Company
 Wisconsin Electric Power Company
 Wisconsin Michigan Power Company
 Wisconsin Power & Light Company
 Wisconsin Public Service Corporation

PUBLICLY-OWNED

*Albany Water, Gas & Light Commission
 Anaheim—Electrical Division
 Austin Electric Department
 *Bristol Electric System (TN)
 *Bryan Municipal Electric System (TX)
 *Burbank Public Service Department
 Central Lincoln People's Utility District (OR)
 Chatanooga Electric Power Board
 *Clatskanie People's Utility District (OR)
 *Cleveland Division of Light & Power (OH)
 *Cleveland Utilities (TN)
 Colorado Springs Department of Public Utilities
 Decatur Electric Department (AL)
 *Detroit Public Lighting Department
 Eugene Water & Electric Company
 Fayetteville Public Works Commission (NC)
 *Florence Electricity Department (AL)
 *Gainesville-Alachua County Regional Electric, Water, and Sewer Utilities Board (FL)
 Garland Electric Department (TX)
 *Glendale Public Service Department (CA)
 *Greenville Light & Power System (TN)
 *Greenville Utilities Commission (NC)
 Huntsville Utilities (AL)
 Imperial Irrigation District (CA)
 *Independence Power & Light Department (MO)
 *Jackson Utility Division—Electric Department (TN)
 Jacksonville Electric Authority (FL)
 Johnson City Power Board (TN)
 Kansas City Board of Public Utilities (KS)
 Knoxville Utility Board (TN)
 *Lafayette Utility System (LA)
 Lakeland Department of Electricity and Water (FL)
 Lansing Board of Water & Light (MI)
 Lincoln Electric System (NB)
 Los Angeles Department of Water and Power
 Lower Colorado River Authority
 *Lubbock Power & Light (TX)
 Memphis Light, Gas & Water Division (TN)
 Modesto Irrigation District (CA)
 *Muscatine Power & Water (IA)
 Nashville Electric Service (TN)
 Nebraska Public Power District
 Omaha Public Power District
 Orlando Utilities Commission (FL)
 *Palo Alto Electric Utility (CA)
 *Pasadena Water & Power Department (CA)
 *Power Authority of New York
 *Port Angeles Light & Water Department (WA)
 *Public Utility District No. 1 of Benton County (WA)
 *Public Utility District No. 1 of Chelan County (WA)
 Public Utility District No. 1 of Clark County (WA)
 Public Utility District No. 1 of Cowlitz County (WA)
 *Public Utility District No. 1 of Douglas County (WA)
 Public Utility District of Grant County (WA)
 Public Utility District No. 1 of Grays Harbor County (WA)

*Public Utility District No. 1 of Lewis County (WA)
 Public Utility District No. 1 of Snohomish County (WA)
 Puerto Rico Water Resources Authority of Puerto Rico
 *Richmond Power & Light (IN)
 Riverside Public Utilities (CA)
 *Rocky Mountain Public Utilities (NC)
 Sacramento Municipal Utility District (CA)
 Salt River Project Agricultural Improvement and Power District (AZ)
 San Antonio Public Service Board (TX)
 *San Francisco Public Utilities Commission
 Santa Clara Electric Department (CA)
 Seattle Department of Lighting (WA)
 South Carolina Public Service Authority
 Springfield City Utilities (MO)
 *Springfield Utilities Board (OR)
 Springfield Water, Light & Power Department (IL)
 Tacoma Public Utilities—Light Division (WA)
 *Taunton Municipal Lighting Plant (MA)
 *Turlock Irrigation District (CA)
 Vernon Municipal Light Department (CA)
 *Wilson Utilities Department (NC)

RURAL ELECTRIC COOPERATIVES

*Appalachian Electric Cooperative
 *Chugach Electric Association
 *Clay Electric Cooperative
 Cumberland Electric Membership Corporation
 *Duck River Electric Membership Corporation
 *First Electric Cooperative Corporation
 *Four County Electric Power Association
 *Gibson County Electric Membership Corporation
 Green River Electric Corporation
 Henderson-Union Rural Electric Cooperative Corporation
 *Jackson Electric Membership Corporation
 *Lee County Electric Cooperative
 *Meriwether Lewis Electric Cooperative
 Middle Tennessee Electric Membership Corporation
 *Moon Lake Electric Association
 *Pederiales Electric Cooperative
 *Pennyrite Rural Electric Cooperative Corporation
 *Singing River Electric Power Association
 *South Central Power Company
 Southern Maryland Electric Cooperative
 *Southern Pine Electric Power Association
 *Southwest Louisiana Electric Membership Corporation
 *Southwest Tennessee Electric Membership Corporation
 *Tri-County Electric Membership Corporation
 *Umatilla Electric Cooperative Association
 *Upper Cumberland Electric Membership Corporation
 Volunteer Electric Cooperative
 *Warren Rural Electric Cooperative
 *West Kentucky Rural Electric Cooperative Corporation

FEDERAL AGENCIES

*Bonneville Power Administration
 *Tennessee Valley Authority
 *Western Area Power Administration

GAS UTILITIES

All utilities listed below had natural gas sales, for purposes other than resale, in excess of 10 billion cubic feet in 1976 or 1977. All, except those marked (*), are covered by PURPA

Title III and NECPA Title II. Utilities marked (*) either do not exceed the threshold in 1977 or do not have residential sales and, therefore, are not covered by NECPA Title II.

INVESTOR-OWNED

Alabama Gas Corporation
 *Alabama-Tennessee Natural Gas Company
 Alaska Gas & Service Company
 *Anadarko Production Company
 Arizona Public Service Company
 Arkansas-Louisiana Gas Company
 Arkansas-Oklahoma Gas Company
 Arkansas Western Gas Company
 Atlanta Gas Light Company
 Baltimore Gas & Electric Company
 Bay State Gas Company
 Boston Gas Company
 Brooklyn Union Gas Company
 Cabot Corporation Utility Division
 California-Pacific Utilities
 Carnegie Natural Gas Company
 Carolina Pipeline Company
 Cascade Natural Gas Corporation
 Central Florida Gas Corporation
 Central Illinois Light Company
 Central Illinois Public Service Company
 Central Louisiana Electric Company
 Chattanooga Gas Company
 Cheyenne Light, Fuel and Power Company
 Cincinnati Gas and Electric Company
 Cities Service Gas Company
 Citizens Gas and Coke Utility
 *Colorado Interstate Gas Company
 Columbia Gas System
 Commonwealth Gas Company
 Connecticut Light & Power Company
 Connecticut Natural Gas Corporation
 Consolidated Edison Company of New York
 Consolidated Gas Supply Corporation
 Consumers Power Company
 Dayton Power & Light Company
 Delmarva Power & Light Company
 East Ohio Gas Company
 *East Tennessee Natural Gas Company
 Elizabethtown Gas Company
 *El Paso Natural Gas Company
 Entex, Incorporated
 Equitable Gas Company
 Florida Gas Company
 *Florida Gas Transmission Company
 Gas Light Company of Columbus
 Gas Service Company
 Gulf States Utilities Company
 Houston Natural Gas Corporation
 Illinois Power Company
 Indiana Gas Company
 Inland Gas Company
 Inter City Gas Limited
 Intermountain Gas Company
 Interstate Power Company
 Iowa Electric Light & Power Company
 Iowa Illinois Gas & Electric Company
 Iowa Power & Light Company
 Iowa Public Service Company
 Iowa Southern Utilities Company
 Kansas-Nebraska Natural Gas Company
 Kansas Power & Light Company
 Kokomo Gas & Fuel Company
 Laclede Gas Company Consolidated
 Lone Star Gas Company
 Long Island Lighting Company
 Louisiana Gas & Electric Company
 Louisiana Gas Service Company
 Louisiana Intrastate Gas Corporation
 Louisville Gas & Electric Company
 Lowell Gas Company
 Madison Gas & Electric Company
 Metropolitan Utilities District of Omaha
 Michigan Consolidated Gas Company

Michigan Gas Utilities Company
 Michigan Power Company
 Minnesota Gas Company
 *Mississippi River Transmission Corporation
 Mississippi Valley Gas Company
 Missouri Public Service Company
 Mobile Gas Service Corporation
 Montana-Dakota Utilities Company
 Montana Power Company
 Mountain Fuel Supply Company
 Nashville Gas Company
 National Fuel Gas Distribution Corporation
 New Jersey Natural Gas Company
 New Orleans Public Service
 New York State Electric & Gas Corporation
 Niagara Mohawk Power Corporation
 North Carolina Natural Gas Corporation
 North Central Public Service Company
 North Penn Gas Company
 North Shore Gas Company
 Northern Illinois Gas Company
 Northern Indiana Public Service Company
 Northern Natural Gas Company
 Northern States Power Company
 Northwest Natural Gas Company
 Northwestern Public Service Company
 Oklahoma Gas & Electric Company
 Oklahoma Natural Gas Company
 Orange & Rockland Utilities
 Pacific Gas & Electric Company
 Panhandle Eastern Pipeline Company
 Pennsylvania Gas & Water Company
 People's Gas, Light & Coke Company
 Peoples Gas System
 Peoples Natural Gas Company
 Philadelphia Electric Company
 Phillips Gas & Oil Company
 Phillips Natural Gas Company
 Phillips Petroleum Company
 Piedmont Natural Gas Company
 Pioneer Natural Gas Company
 Providence Gas Company
 Public Service Company of Colorado
 Public Service Company of North Carolina
 Public Service Electric & Gas Company
 Rochester Gas & Electric Corporation
 San Diego Gas & Electric Company
 Sierra Pacific Power Company
 South Carolina Electric & Gas Company
 South Jersey Gas Company
 Southeast Alabama Gas District
 Southeastern Michigan Gas Company
 Southern California Gas Company
 Southern Connecticut Gas Company
 Southern Indiana Gas & Electric Company
 Southern Natural Gas Company
 Southern Union Gas Company
 Southwest Gas Corporation
 Terre Haute Gas Corporation
 *Texas Eastern Transmission Corporation
 Texas Utilities
 Tucson Gas & Electric Company
 UGI Corporation
 Union Gas Systems
 Union Light, Heat & Power Company
 United Cities Gas Company
 United Gas Pipeline Company
 Virginia Electric Power Company
 Washington Gas Light Company
 Washington Natural Gas Company
 Washington Water Power Company
 West Ohio Gas Company
 Western Gas Corporation
 Western Kentucky Gas Company
 Western Slope Gas Company
 Wisconsin Fuel & Light Company
 Wisconsin Gas Company
 Wisconsin Natural Gas Company
 Wisconsin Power & Light Company
 Wisconsin Public Service Corporation

PUBLICLY-OWNED

City of Richmond, Virginia, Department of Public Utilities
 City Public Service Board (San Antonio)
 Springfield City Utilities (MO)
 Colorado Springs Department of Public Utilities
 Long Beach Gas Department
 Memphis Light, Gas & Water Division
 Philadelphia Gas Works

Issued in Washington, D.C., December 18, 1978.

JERRY L. PFEFFER,
*Acting Assistant Administrator
 for Utility Systems, Economic
 Regulatory Administration,
 Department of Energy.*

[FR Doc. 78-35545 Filed 12-21-78; 8:45 am]

[6740-02-M]

Federal Energy Regulatory Commission

[Docket No. R-406]

DISTRIGAS CORP. AND DISTRIGAS OF MASSACHUSETTS CORP.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Distrigas Corporation ("Distrigas") and Distrigas of Massachusetts Corporation ("DOMAC") on December 1, 1978, tendered for filing:

Distrigas Corporation:
 First Revised Sheet No. 4
 First Revised Sheet No. 5

Distrigas of Massachusetts Corporation:
 First Revised Sheet No. 53
 First Revised Sheet No. 54

to their respective FERC Gas Tariffs. These revised sheets are submitted to reflect changes made pursuant to FERC Order No. 13 issued October 18, 1978, in Docket No. R-406. Additionally, the revised tariff sheets of Distrigas reflect a clarification relating to the mechanics of operation of Distrigas' purchased gas adjustment clause as it pertains to demurrage charges.

No change in rate is involved in these revised tariff sheets.

Distrigas and DOMAC request that the proposed tariff sheets become effective January 1, 1979.

A copy of this filing is being served upon all affected parties and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such peti-

tions or protests should be filed on or before December 22, 1978.

Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35605 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

EAST TENNESSEE NATURAL GAS CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on December 1, 1978, East Tennessee Natural Gas Company (East Tennessee) tendered for filing the following revised tariff sheets to its FERC Gas Tariff, Sixth Revised Volume No. 1, to be effective January 1, 1979.

First Revised Sheet No. 74B
 Second Revised Sheet No. 74C
 Third Revised Sheet Nos. 66, 69B and 74D
 Fourth Revised Sheet Nos. 67 and 69A
 Sixth Revised Sheet No. 69

East Tennessee states that the purpose of the revised tariff sheets is to revise (1) the PGA clause in the General Terms and Conditions of its tariff to conform to the requirements of Order No. 13 and (2) the Gas Research Institute Rate Adjustment provision in its tariff to conform to the requirements of Opinion No. 30.

East Tennessee states that copies of the filing have been mailed to all of its jurisdictional customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of

this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35606 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

FLORIDA GAS TRANSMISSION CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Public Notice is hereby given that on December 1, 1978 Florida Gas Transmission Company (Florida Gas) filed in the instant docket pursuant to the Commission's Order No. 13, issued October 18, 1978, proposed changes to Florida Gas' FERC Gas Tariff, Original Volume No. 1, consisting of the following tariff sheets:

Second Revised Sheet No. 22-C
 First Revised Sheet No. 22-D
 First Revised Sheet No. 22-E
 Original Sheet No. 22-E.1

Florida Gas states that the purpose of the filing is to conform its Purchased Gas Adjustment Clause (PGA) with Order No. 13 and the amendments required thereby to 18 CFR § 154.38(d). In that regard, Florida Gas advises that it has modified its PGA to include carrying charges on the net balances of A/C 191 and A/C 283 or A/C 190, as appropriate, inasmuch as the principles of interperiod income tax allocation have been adopted for unrecovered purchase gas cost account balances. Further, as directed by Order No. 13, Florida Gas has revised the effective dates of its PGA filings to April 1 and October 1.

Florida Gas requests that the instant filing to be made effective on the proposed effective date of January 1, 1979.

Additionally, Florida Gas states that pursuant to the Commission's Regulations the instant tariff filing has been mailed to each affected customer and the Florida Public Service Commission.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 22, 1978, file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, a petition to intervene or protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 C.F.R. 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make protestants parties to

the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35607 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

GRANITE STATE GAS TRANSMISSION, INC.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Granite State Gas Transmission, Inc. (Granite State), 66 Market Street (P.O. Box 508, Portsmouth, New Hampshire 03801, on December 1, 1978, tendered for filing with the Federal Energy Regulatory Commission, the following revised tariff sheets for effectiveness January 1, 1979 in its FERC Gas Tariff, Original Volume No. 1:

First Revised Sheet No. 32B
Second Revised Sheet No. 32C
First Revised Sheet No. 32D
Original Sheet No. 32E
Original Sheet No. 32F

According to Granite State, the foregoing tariff sheets establish a revised Purchased Gas Cost Rate Adjustment provision in Section XX of the General Terms and Conditions in its tariff in compliance with the requirements of the Commission's Order No. 13 in Docket No. R-406.

Granite State further states that copies of its filing have been served on its only jurisdiction customer, Northern Utilities, Inc., and the Public Utility Commission's of the State of Maine and New Hampshire.

Any person desiring to be heard or the protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with

the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35608 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

INTER-CITY MINNESOTA PIPELINES, LTD., INC.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Inter-City Minnesota Pipelines, Ltd., Inc. (Inter-City) on December 1, 1978, tendered for filing proposed changes in its FERC Gas Tariff, Original Volume No. 1, as follows:

First Revised Sheet No. 56
Original Sheet No. 56-A
First Revised Sheet No. 61-C
Original Sheet No. 61-D
Second Revised Sheet No. 63
First Revised Sheet No. 64

Inter-City states that the above tariff sheets are filed solely for the purpose of conforming the existing tariff PGA clause to the requirements of Commission Order 13-A of November 27, 1978, and to Section 154(4)(d)(viii) of the Commission's Rules and Regulations.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35613 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

KENTUCKY WEST VIRGINIA GAS CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Kentucky West Virginia Gas Co. (Kentucky West) on

November 29, 1978, tendered for filing with the Commission the following revised tariff sheets to Kentucky West's FERC Gas Tariff, First Revised Volume No. 1, to become effective January 1, 1979:

First Revised Sheet No. 24
First Revised Sheet No. 25
First Revised Sheet No. 26
Eighth Revised Sheet No. 27

The revised tariff sheets incorporate the amendments to Kentucky West's purchased gas cost adjustment provisions required by Commission Order No. 13 and also reflect the jurisdiction of the Federal Energy Regulatory Commission (rather than the Federal Power Commission) and the laws and regulations it administers.

Kentucky West states that a copy of its filing has been served upon Kentucky West's jurisdictional customers and the Public Service Commission of Kentucky.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35609 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

LOUISIANA-NEVADA TRANSIT CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Louisiana-Nevada Transit Company (Louisiana-Nevada) on November 27, 1978, tendered for filing proposed changes in its FERC Gas Tariff, Original Volume No. 1, as follows:

Second Revised Sheet No. 12E
First Revised Sheet No. 12G
First Revised Sheet No. 12H

These proposed changes to be effective January 1, 1979, are being filed pursuant to Order No. 13, issued by the Federal Energy Regulatory Commission on October 18, 1978. These re-

vised tariff sheets limit Louisiana-Nevada to two PGA filings annually by eliminating the pipeline tracking provision at periods of time other than the semiannual dates (June 1 and December 1) and provides for interest calculated on the prior months ending balance of the Unrecovered Purchased Gas Cost Account, exclusive of accumulated interest, and after reflecting interperiod income tax allocations.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35610 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

MICHIGAN WISCONSIN PIPE LINE CO.

Proposed Amendments to Purchased Gas Costs Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Michigan Wisconsin Pipe Line Company (Michigan Wisconsin) on December 1, 1978, tendered for filing proposed changes in its FERC Gas Tariff, Second Revised Volume No. 1 as follows:

Third Revised Sheet No. 27A
Second Revised Sheet No. 27B
Second Revised Sheet No. 27C
Second Revised Sheet No. 27D
Second Revised Sheet No. 27E
First Revised Sheet No. 27E(i)
First Revised Sheet No. 27E(ii)
First Revised Sheet No. 27E(iv)

Michigan Wisconsin states that the revised tariff sheets reflect amendments to Michigan Wisconsin's purchased gas cost adjustment tariff provisions required by the Commission in Order No. 13. The amendments, to become effective January 1, 1979, provide that: (1) purchased gas cost adjustments shall not be filed more frequently than semiannually and shall have an effective date of May 1 and November 1; and (2) carrying charges be computed monthly on the net bal-

ances in Account 191 and the related amounts recorded in the Accumulated Deferred Income Tax Accounts 283 or 190, as appropriate. Michigan Wisconsin is also filing revisions to Section 16, Research and Development Adjustment, and Section 17 Gas Research Institute Charge Adjustment Provision, to conform the effective dates of any adjustments made thereunder to the dates utilized in Section 5.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35611 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

MIDWESTERN GAS TRANSMISSION CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on December 1, 1978, Midwestern Gas Transmission Company (Midwestern) tendered for filing the following revised tariff sheets to its FERC Gas Tariff, Third Revised Volume No. 1, to be effective January 1, 1979.

Third Revised Sheet Nos. 83 and 95G
Fourth Revised Sheet Nos. 81 and 82
Fifth Revised Sheet No. 85

Midwestern states that the purpose of the revised tariff sheets is to revise (1) the PGA clause in the General Terms and Conditions of its tariff to conform to the requirements of Order No. 13 and (2) the Gas Research Institute Rate Adjustment provision in its tariff to conform to the requirements of Opinion No. 30.

Midwestern states that copies of the filing have been mailed to all of its jurisdictional customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35612 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

MOUNTAIN FUEL RESOURCES, INC.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on December 1, 1978, Mountain Fuel Resources, Inc. (Resources) pursuant to Section 154.62 and 154.38 of the Commission's Regulations under the Natural Gas Act, filed Seventh Revised Sheet No. 7 and First Revised Sheet No. 23 to its FERC Gas Rate Schedule No. 1. Resources states that the filed Seventh Revised Tariff Sheet No. 7 relates to the Unrecovered Purchased Gas Cost Account of the Purchased Gas Adjustment Provisions authorized by RP74-14. More specifically, the tariff sheet reflects a net decrease from that currently being collected of (7.58) cents per Mcf to be effective January 1, 1979.

Any person desiring to be heard and to make any protest with reference to said filing should on or before December 22, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C., 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing must file petitions to intervene in accordance with

the Commission's Rules. Resources tariff filing is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35614 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP76-285, ET AL.]

MOUNTAIN FUEL RESOURCES INC., ET AL.

Order Consolidating Proceedings, Granting and Denying Petitions To Intervene and Establishing Hearing Procedures

DECEMBER 15, 1978.

In the matter of Mountain Fuel Resources Inc., et al., Docket Nos. CP76-285, et al. (Clay Basin); El Paso Natural Gas Company, Docket No. CP76-87 (Rhodes Reservoir); El Paso Natural Gas Company, Docket No. CP78-172 (Barker Creek Dome); Western Gas Interstate Company, Docket No. CP78-257 (Barker Creek Dome); and Supron Energy Corporation, Docket No. CI78-506 (Barker Creek Dome).

On October 13, 1978, El Paso Natural Gas Company (El Paso), filed in each of the dockets listed above a motion to consolidate for hearing and decision the following:

(1) Certificate issues remaining in the proceeding in Docket Nos. CP76-285, et al., concerning the participation of El Paso and Clay Basin Storage Company (Storage Company) in the Clay Basin storage field project;

(2) El Paso's pending certificate application in Docket No. CP76-87 concerning El Paso's Rhodes Reservoir storage project; and

(3) The pending certificate applications of El Paso at Docket No. CP78-172, Western Gas Interstate (WGI) at Docket No. CP78-257 and Supron Energy Corporation (Supron) at Docket No. CI78-506, which concern El Paso's proposed Barker Creek Dome storage project.

These proceedings involve three separate storage projects in which El Paso is participating in differing fashions but with a common purpose: to provide a source of protection on peak days in winter for customers included in the Priority 1 and Priority 2 classes in El Paso's current interim curtailment plan and located east of the State of California. The issue of the need for the projects to provide such protection, as well as other issues, has been raised in each of the proceedings in pleadings and, in one case, in pre-hearing conferences. We hereby grant El Paso's motion and consolidate for hearing and decision these proceedings, all as more fully set forth below.

I. RHODES RESERVOIR STORAGE PROJECT

On September 17, 1975, El Paso filed an application, pursuant to Section 7(c) of the Natural Gas Act, for a certificate of public convenience and necessity, of unlimited duration to permit El Paso to use the Rhodes Reservoir for storage and to make a sale of gas to Southern California Gas Company (SoCal).¹ In this application El Paso requested the issuance of a temporary certificate to go forward with the proposed Rhodes Reservoir operations pending the Commission's final determination of El Paso's request for a permanent certificate.

The Commission granted El Paso a temporary certificate on November 6, 1975, and has renewed the authorization each year, including the most recent temporary certificate granted on November 17, 1978.²

On September 27, 1977, the Commission issued an order in Docket No. CP76-87, noting that in its Opinion Nos. 800 and 800-A and in the decision of the United States Court of Appeals for the District of Columbia Circuit in *City of Willcox, et al. v. FPC*, 567 F.2d 394 (1977), cert. den., 98 S.Ct. 724 (1978), it was ordered that the Rhodes project's stored volumes be used to make restitution for the discrimination found in those opinions. See, Opinion No. 800-B, Docket Nos. CP74-289, et al., December 30, 1977, at 5-10.

The Commission accordingly amended the temporary certificate issued in Docket No. CP76-87 on July 28, 1977, to provide that:

¹The application specifically requested authorization for the following:

(1) The operation of facilities previously installed under limited-term authorization for the injection of natural gas into and withdrawal of natural gas from Rhodes Reservoir;

(2) The transportation and sale of natural gas withdrawn from the reservoir for the benefit of El Paso's east-of-California (EOC) customers classified as having Priority 1 and 2 requirements; and

(3) The transportation and sale of natural gas so withdrawn from the reservoir for the benefit of SoCal as compensation for the previous diversion of volumes from SoCal pursuant to an agreement between El Paso and SoCal for the protection of service to EOC Priority 1 and Priority 2 requirements.

On October 10, 1973, the Commission had issued El Paso a permanent certificate in Docket No. CP73-334 authorizing it to construct and operate the facilities necessary to reactivate the reservoir as a storage project, and to transport and sell certain volumes from this project during the 1973-74 winter heating season.

²The Commission order of July 28, 1977, extending a temporary certificate through April 30, 1978, further provided that El Paso could no longer deliver volumes to SoCal as was sought in the initial application for a permanent certificate finding that the SoCal-El Paso agreement described in the application was limited to the 1975-76 and 1976-77 winter heating seasons.

(1) Any authorization granted in that docket not be inconsistent with Opinion Nos. 800, 800-A and *City of Willcox, et al. v. FPC*; and

(2) That any injections of natural gas into the Rhodes storage project authorized in other dockets shall not be affected by the authorization granted in Docket No. CP76-87.³

On March 15, 1978, the Commission issued an order in Docket No. CP76-87 and in other proceedings severing from those proceedings concerning the permanent certificate application for the Rhodes project, as well as from the proceedings concerning the permanent certificate applications of El Paso to operate the Clay Basin and Barker Creek Dome projects, the following matters:

(1) The proper classification of storage gas among the priorities set in El Paso's current interim curtailment plan; and

(2) The proper procedures or service rules El Paso must follow in operating its EOC storage projects.

The Commission found that the appropriate proceeding to consider these matters is that concerning the remand of *City of Willcox* in Docket Nos. RP72-6 and RP76-38, wherein the same matters concerning El Paso's California storage projects were being litigated.

As stated above, on October 13, 1978, El Paso filed its motion to consolidate the remaining proceedings in Docket No. CP76-87 with the proceedings concerning its other two EOC storage projects.

II. CLAY BASIN FIELD STORAGE PROJECT

In its order of September 30, 1977, in Docket Nos. CP76-285, et al., the FPC set forth details of El Paso's participation in the Clay Basin Storage Field, which is owned and operated by other parties. It stated therein that El Paso had filed an application, in Docket No. CP77-289, seeking Section 7(c) authorization to store gas at the Clay Basin field, through December 31, 1979, for the purposes of acquiring additional protection for its EOC Priority 1 and Priority 2 customer requirements for delivery on winter peak demand days.

El Paso's application for a certificate to participate, on an interim basis, in the Clay Basin storage project was consolidated for hearing with the applications of parties participating in the field on a permanent basis by the order of September 30, 1977. The various participants in the project have

³On November 28, 1977, Arizona Electric Power Cooperative, Inc. (AEP) and the City of Willcox, Arizona filed a joint petition for review of the Commission's order of July 28, 1977, in Docket No. CP76-87 with the U.S. Court of Appeals for the District of Columbia Circuit in Docket No. 77-2053.

each sought and received a series of temporary certificates permitting project operations pending final action on their applications for permanent certification.⁴

On July 3, 1978, the Commission issued an order, in Docket Nos. CP76-285, *et al.*, in which it defined certain issues to be addressed in the hearing concerning Clay Basin Field.⁵ Hearings were held on certain issues. The issues raised by the pleadings concerning El Paso's participation in the field were reserved for a later phase of the proceeding, which is currently in the discovery stage.

In the meantime, El Paso filed the previously mentioned motion to consolidate the remaining proceeding in Docket No. CP76-285, *et al.*, with the proceedings concerning its other EOC storage projects.

III. BARKER CREEK DOME STORAGE PROJECT

On January 24, 1978, El Paso filed an application, pursuant to Section 7(c), for authorization, *inter alia*, to construct and operate facilities to store gas at the Barker Dome field located in San Juan County, New Mexico and La Plata County, Colorado. El Paso sought a certificate of unlimited duration. It did not request a temporary certificate to operate the project. As stated above, El Paso's application states that the Barker Dome project is to be used as a means for El Paso to meet EOC Priority 1 and Priority 2 requirements on winter peak days.

El Paso has entered into two agreements in order to use the Barker Dome project. It has entered a lease agreement with the Mountain Ute Indian tribe, which owns the land on which the proposed project would be located, and Supron, which held rights to extract gas from the reservoir. Under the lease agreement, the Mountain Utes would grant the right to El Paso to establish and operate a gas storage project in the reservoir for a term of ten years and for so long thereafter as El Paso continues to use the project. El Paso, in turn, has agreed to pay the Mountain Utes an annual rent. Supron agrees to relinquish its right to produce gas from the field. As part of the lease agreement, El Paso entered into a stipulation with Supron and the Mountain Utes as to the estimated amounts of recoverable indigenous gas in the reservoir.

In order to compensate Supron for relinquishing its right to purchase gas from the reservoir, El Paso has entered into a sublease agreement with Supron. Under this agreement, El Paso, in essence, would make available to an affiliate of Supron, Southern Union Gathering Company (Gathering Company), the equivalent of the amounts of gas stipulated to be recoverable at present from the field, as well as provide additional compensation to Supron.

In order to carry out its part of the agreement, Supron filed, on March 1, 1978, an application for authorization, pursuant to Section 7(c), in Docket No. CI78-506, to make the sales to Gathering Company.

On March 28, 1978, WGI filed an application, in Docket No. CP78-257, for a certificate, pursuant to Section 7(c), authorizing the transportation needed to permit El Paso to use the Barker Dome reservoir.

As stated above, El Paso filed its motion, on October 13, 1978, to consolidate for hearing and decision the proceedings concerning the three applications relating to El Paso's proposed Barker Dome project with the proceedings concerning the Clay Basin and Rhodes reservoir projects.

CONSOLIDATED HEARING

We herein consolidate for hearing and decision these certificate applications in order to serve several purposes. Most importantly, we seek to eliminate the possibility of conflicting decisions regarding the need for all or any one of the three storage projects involved. As stated above, the issue of whether the projects are needed to serve their intended purposes has been raised in each of the proceedings. By disposing of these applications in a single proceeding the public interest is served in many ways, including providing a measure of certainty to El Paso as to which projects, if any, will have Commission approval.

We further hope that consolidation of these dockets will promote economy in the litigation concerning these applications. We urge the parties to make every effort to lessen the time and expense of the consolidated proceedings by, for example, presenting and cross-examining witnesses responsible for more than one project at a single time. We have stated above those matters that have been severed from these proceedings by prior Commission orders and we urge the parties to refrain from attempting to raise such issues in the consolidated proceedings; further, issues that are appropriately in other proceedings should not be raised. This direction should not be understood as precluding discussion of how the resolution of issues in other proceedings will impact upon the consolidated proceeding.

We find that the most expeditious course to follow would be to add the applications concerning the Barker Dome and Rhodes projects to the Clay Basin proceeding, in which procedural dates have been set. In order to promote economy of effort in the consolidated proceeding we direct the applicants and interveners in the various proceedings to appear before the Presiding Administrative Law Judge assigned to the Clay Basin proceeding and be prepared to present their views on the scope of the issues to be tried and, most importantly, on the most expeditious and economical procedure to follow in disposing of these issues.

As an initial effort to expedite the proceeding, we suggest that the parties discuss completely the issues surrounding general system needs. Thereafter the parties should discuss the remaining issues surrounding each of the proposed projects.

We will grant the following petitions to intervene filed in Docket No. CP78-172:

Southern California Gas Company
Pacific Gas and Electric Company
The State of New Mexico Energy Resources Board
Asarco, Inc., *et al.*
Tucson Gas & Electric Company
Southern Union Company
The Peoples of the State of California and the Public Utilities Commission of the State of California
Arizona Electric Power Cooperative, Inc., *et al.*
Mountain Fuel Resources, Inc.
Arizona Public Service Company

In addition, we will grant intervention to the following parties in Docket No. CI78-506:

Western Gas Interstate Company
Arizona Electric Power Cooperative

Finally, we will grant the following petition to intervene in Docket No. CP78-257:

State of New Mexico Energy and Minerals Department

The petitions to intervene filed by Arizona Public Service Company in Docket No. CP78-172 and the State of New Mexico Energy and Minerals Department in Docket No. CP78-257 were filed out of time. We grant the former's petition because good cause has been shown for the late filing. We grant the latter's petition because it is a department of a state government.

The following petitions to intervene filed out of time will be denied for not comporting with Section 1.8(d) of the

⁴On January 16, 1978, AEPCO filed a petition for review of the Commission's orders of September 30, 1977, and November 28, 1977, in Docket Nos. CP76-285, *et al.*, which granted temporary certificates, in the U.S. Court of Appeals for the District of Columbia Circuit in Docket No. 78-1043. On February 6, 1978, AEPCO filed a petition for review of the order of December 6, 1977, which clarified the order of September 30, 1977, with the D.C. Circuit Court in Docket No. 78-1101.

⁵On October 16, 1978, AEPCO filed a petition for review of the order of July 3, 1978, issued in Docket Nos. CP76-285, *et al.*, with the District of Columbia Circuit in Docket No. 78-2026.

Commission's Rules of Practice and Procedure, which requires that a showing of good cause be made in order for the Commission to accept a late petition:

Salt River Project Agricultural Improvement and Power District (Docket No. CP78-172)

Pacific Gas and Electric Company (Docket No. CI78-506)

See, *Trunkline Gas Company*, Docket No. CP78-338, *et al.*, Order issued November 15, 1978, at 5-6.

Further, we will find that good cause exists to permit each of the interveners who have been granted intervention in the various Barker Dome and Rhodes projects proceedings, including those interventions granted herein, to intervene without further filing in the Clay Basin proceeding.

The Commission finds:

(1) It is necessary and appropriate in carrying out the provisions of the Natural Gas Act that a public hearing be held on the matters involved and the issues presented in these proceedings.

(2) Due to the related nature of the applications and the common questions of law and fact involved, it is appropriate to consolidate the proceedings in the above captioned dockets.

(3) Participation by the interveners in the various dockets in the consolidated proceeding may be in the public interest. Good cause exists for permitting intervention in the consolidated proceeding of those previously permitted to intervene in any one of the individual dockets and the several petitions to intervene timely filed in the Barker Dome proceedings (Docket Nos. CP78-172, CP78-257 and CI78-506) and for permitting the late intervention of Arizona Public Service Company in Docket No. CP78-172 and the State of New Mexico Energy and Minerals Department in Docket No. CP78-257.

(4) Good cause does not exist to permit the late-filed intervention of Salt River Project Agricultural Improvement and Power District in Docket No. CP78-172 or of Pacific Gas and Electric Company (PG&E) in Docket No. CI78-506.

The Commission orders:

(A) These proceedings are hereby consolidated for purposes of hearing and disposition.

(B) Pursuant to the authority of the Natural Gas Act, particularly sections 7 and 15 thereof, the Commission's Rules of Practice and Procedure (18 CFR Part L), and the Regulations under the Natural Gas Act (18 CFR Chapter I, Subchapter E), a prehearing conference shall be held on January 4, 1979 in Docket Nos. CP76-285, *et al.*, commencing at 10 a.m. in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, to

discuss procedural issues and the clarification of issues.

(C) The Administrative Law Judge currently assigned to Docket Nos. CP76-285, *et al.*, shall preside at the prehearing conference in this proceeding, with authority to establish and change all procedural dates, and to rule on all motions (with the sole exception of motions to consolidate and sever and motions to dismiss), as provided for in the Rules of Practice and Procedure.

(D) The consolidated proceeding ordered herein shall be known as: Mountain Fuel Resources, Inc., Docket Nos. CP76-285, *et al.* (Consolidated El Paso Storage Certificates Proceeding).

(E) The above-mentioned existing interveners in the various dockets, as well as those permitted to intervene herein, are permitted to intervene in the consolidated proceeding subject to the rules and regulations of the Commission; *Provided, however*, that the participation of such interveners shall be limited to matters affecting asserted rights and interests as specifically set forth in their petitions to intervene; and *Provided further*, that the admission of such interveners shall not be construed as recognition by the Commission that they might be aggrieved because of any order of the Commission entered in this proceeding.

(F) The petitions to intervene of Salt River Project Agricultural Improvement and Power District in Docket No. CP78-172 and of Pacific Gas and Electric Company in Docket No. CI78-506 are hereby denied.

By the Commission.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc. 78-35598 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

MOUNTAIN FUEL SUPPLY CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take Notice that on December 1, 1978, Mountain Fuel Supply Company (Mountain Fuel) pursuant to Section 154.38 of the Commission Regulations, under the Natural Gas Act, filed First Revised Sheet Nos. 3-B and 3-D to its FERC Gas Tariff Original Volume No. 1. Mountain Fuel states that the filed First Revised Sheet Nos. 3-B and 3-D relates to the timing of PGA filings to be made by Mountain Fuel and to the application of carrying charges on the end of month balance in Account 191 and is filed pursuant to Commission Order No. 13 issued October 18, 1978, in Docket No. R-406.

Any person desiring to be heard and to make any protest with reference to said filing should on or before December 22, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it but will not serve to make the protestants parties to the proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing must file petitions to intervene in accordance with the Commission Rules. Mountain Fuel Supply Company's tariff filing is on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35615 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

NATURAL GAS PIPELINE CO. OF AMERICA

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on December 1, 1978, Natural Gas Pipeline Company of America (Natural), tendered for filing proposed changes in its FERC Gas Tariff, Third Revised Volume No. 1 as follows:

Tenth Revised Sheet No. 119
Third Revised Sheet No. 120
Eighth Revised Sheet No. 120-A
Second Revised Sheet No. 120-B
Third Revised Sheet No. 121

Natural states that the proposed changes, to become effective January 1, 1979 were made to revise its existing Purchase Gas Adjustment (PGA), clause pursuant to the amended provisions of Section 154.38 of the Commission's Regulations that will become effective January 1, 1979, under FERC Order Nos. 13, issued October 18, 1978, and 13-A, issued November 27, 1978, at Docket No. R-406. Revisions to the existing PGA clause have also been made to conform it with certain account numbering charges as set out in Commission Order No. 6, issued April 28, 1978, at Docket No. RM77-21.

Copies of this filing were served upon the Company's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N. E., Washington, D. C. 20426, in accordance with Section 1.8 and 1.10 of the

Commission's Rules of Practice and Procedures (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken by will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35616 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

NORTHWEST PIPELINE CORP.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on November 30, 1978, Northwest Pipeline Corp. ("Northwest") tendered for filing the following tariff sheets as part of Northwest's FERC Gas Tariff, Original Volume No. 1: Second Revised Sheet No. 60.

As more fully explained in the instant filing, said tariff sheet will, when accepted for filing and permitted to become effective, conform Northwest's Purchased Gas Cost Adjustment Provision of its Volume No. 1 Tariff to the guidelines established by the Commission in Order No. 13 at Docket No. R-406.

In addition, to comply with the Commission's Order at Docket No. RM79-1, Northwest has advised the Commission in the instant filing that it elects to reflect changes in purchased gas costs through its PGA clause.

The proposed effective date of the tendered tariff sheet is January 1, 1979. A copy of this filing has been served on Northwest's jurisdictional customers and interested State commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.9, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene.

Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35617 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

PACIFIC INTERSTATE TRANSMISSION CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Pacific Interstate Transmission Company on December 1, 1978 tendered for filing as part of its FERC Gas Tariff, Original Volume No. 2, the following sheets:

First Revised Sheet No. 36.

Second Revised Sheet No. 38.

The proposed effective date of these tendered tariff sheets is January 1, 1979.

The tariff sheets listed above are issued pursuant to Order No. 13 issued October 18, 1978 in Docket No. R-406. This order amends the Purchased Gas Cost Adjustment Provisions in natural gas pipeline tariffs to provide for the inclusion of carrying charges on the balance in the Unrecovered Purchased Gas Cost Account 191 and related amounts in Account 283 or 130, as appropriate.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, Washington, DC 20462, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35618 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP77-7]

PANHANDLE EASTERN PIPE LINE CO.

Petition To Amend

DECEMBER 12, 1978.

Take notice that on November 22, 1978, Panhandle Eastern Pipe Line Company (Panhandle), P.O. Box 1642,

Houston, Texas 77001, filed in Docket No. CP77-7 a petition to amend the order of November 24, 1976, in the instant docket (56 FPC) (order) pursuant to Section 7(c) of the Natural Gas Act and Section 2.79 of the Commission's General Policy and Interpretations (18 CFR 2.79), to authorize the continued transportation of natural gas on behalf of Chemetals Corporation (Chemetals), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that Chemetals has agreed to purchase, pursuant to an assignment and assumption agreement dated May 26, 1978, certain assets from Diamond Shamrock Corporation (Diamond), including a manganese oxide plant near Baltimore, Maryland. It is stated that Panhandle has been granted authority by the order to transport up to 1,000 Mcf of gas per day for Diamond's manganese plant. It is further stated that on August 4, 1978, Panhandle filed a petition to amend the order to reflect the change in the gas purchaser resulting from the sale of the manganese plant from Diamond to Chemetals.

In the instant petition to amend, Panhandle seeks modification of the order to extend the term of the transportation service for an additional two years (to November 30, 1980) and to reduce the volumes of gas to be transported from 1,000 Mcf per day (the original maximum daily volume) to a firm 480 Mcf per day plus 320 Mcf per day on a best efforts basis.

It is stated that the gas would continue to be delivered to Panhandle at Diamond's McKee Plant in Moore County, Texas, transported by Panhandle with delivery to Columbia Gas Transmission Corporation (Columbia) at the existing delivery point in Ohio, and further transported and delivered by Columbia to Baltimore Gas and Electric Company (BG&E) which in turn would deliver to Chemetals. No additional facilities are necessary to be constructed to perform Panhandle's portion of the service.

It is stated that Panhandle's monthly transportation charge for the service to be performed for Chemetals would be \$4,238 for the 480 Mcf of gas transported per day for Chemetals. Such charge would be subject to increase or decrease by an amount equal to 29.03 cents per Mcf of gas, if the volumes transported varies from the firm volume of 480 Mcf per day, it is asserted. Panhandle would also retain 12 percent of the volumes delivered to it for compressor fuel usage, it is indicated.

It is further stated that the modifications requested are required because Chemetals faces a projected 45 percent curtailment by its supplier for

the coming winter season. Such a curtailment, if it is started, would result in layoffs in the aforementioned manganese plant, with a concomitant ripple effect in other industries.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35599 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. RP71-119 et al.]

PANHANDLE EASTERN PIPE LINE CO. ET AL.

Order Granting Petition for Relief From Payback Order, Consolidating Proceedings, and Granting Intervention

DECEMBER 15, 1978.

PROCEDURAL HISTORY

On May 22, 1978, Anchor Hocking Corporation (A-H), Docket No. RP74-31-24, filed a petition for relief from the Commission's¹ order of August 31, 1976, dismissing an earlier petition for extraordinary relief and ordering payback. A-H now seeks reversal of the payback order.

On August 11, 1978, Hercules Incorporated (Hercules), Docket No. TC78-34, filed a similar petition, requesting relief from the payback orders issued in Docket No. RP74-31-22 on October 31, 1974; July 30, 1975; April 1, 1976, and September 3, 1976.

Both petitioners base their requests on the allegedly advantageous treatment afforded to similarly situated customers on the Panhandle Eastern Pipe Line Company system (Panhandle). A review of the Commission's actions in granting relief to Panhandle's

customers from payback obligations incurred under an unjust and unreasonable interim curtailment plan compels us to grant the requested relief out of equitable considerations.

The curtailment priority guidelines of Order No. 467-B, Docket No. R-469 (49 FPC 583), created a distinction between firm and interruptible pipeline customers. Both Hercules and A-H had interruptible contracts with Panhandle, and faced complete curtailment under a 467-B plan whenever Panhandle was required to curtail its priority No. 3 customers. The order issued in Docket No. RP71-119 on November 6, 1973, implemented a 467-B type plan on the Panhandle system effective November 1, 1973.

During the fall of 1973, Panhandle's interruptible customers filed numerous petitions requesting extraordinary relief. Many of these interruptible customers needed natural gas for their feedstock or process requirements. At least six different administrative law judges presided over hearings on these petitions. Many petitioners received temporary relief pending final Commission action on their petitions for relief. Most such relief was subject to a payback requirement, i.e., a future reduction of gas consumption below a company's curtailment allocation to restore the excess gas used during periods of extreme shortage.

On February 27, 1976, the FPC issued Opinion No. 754, which prescribed a permanent curtailment plan for the Panhandle system and which abolished the firm-interruptible distinction. It is clear that had this curtailment plan been in effect during the interim period, Hercules and A-H would not have required extraordinary relief and would not have incurred payback obligations. We must decide, therefore, how to treat the payback obligations incurred by A-H and Hercules under the 467-B plan.

A. HERCULES

On September 4, 1974, Hercules filed its extraordinary relief petition.² Hercules' plant at Louisiana, Missouri produces anhydrous ammonia, used principally in the manufacture of fertilizers, and ammonium nitrate prills, an explosive used to mine coal. By order issued October 31, 1974 the FPC granted temporary extraordinary relief for feedstock and process uses to permit ammonia production at full capacity. This relief pending hearing was subject to a payback condition.

The initial decision³ provided Hercules with a minimum of 4,600 Mcf of

gas per day, subject to a payback condition. This extraordinary relief gas was delivered subject only to the curtailment priority of Category 1 (residential and small commercial uses). The FPC affirmed the initial decision, dismissed the petition for extraordinary relief as moot, and ordered payback.⁴

On March 26, 1976, Hercules filed a complaint⁵ requesting waiver of its payback obligations in view of Opinion No. 754, which eliminated the firm-interruptible distinction. The FPC dismissed the complaint on April 1, 1976.⁶

Hercules' application for rehearing was denied by operation of law, and it appealed to the U.S. Court of Appeals for the Third Circuit. Hercules sought to be excused from further payback obligations and requested return of the gas already paid back.⁷

The Court held "that all payback obligations incurred by Hercules as a result of the firm-interruptible distinction are now unenforceable."⁸ The Court added:

In so holding we do not mean to indicate that Hercules is entitled to restitution for all injuries suffered as a result of Panhandle's unlawful curtailment plan. Unlike rate overcharges prior allocations of gas under a plan now found to have been unreasonable cannot be easily refunded. Not all parties injured as a result of the necessity to react quickly to the natural gas crisis can be made whole.⁹

Upon remand, the FPC released Hercules from any further payback obligation.¹⁰ At that time Hercules claims to have repaid 1,107,000 Mcf of its 1,550,000 Mcf extraordinary relief obligations.

B. ANCHOR-HOCKING

On December 12, 1974, A-H also filed a petition for extraordinary relief.¹¹ A-H requested relief of 790 Mcf/d to operate the feeders and lehrs

les to the 4,600 Mcf recommended by the Initial Decision.

⁴Order Dismissing Petition for Extraordinary Relief and Ordering Payback, September 3, 1976.

⁵Docket No. RP76-75.

⁶Order Denying Motion and Request and Dismissing Complaint, April 1, 1976.

⁷Hercules, Inc. v. FPC, No. 76-1593 Brief for Petitioner, August 23, 1976, at 34, requested return of "the volumes of gas withheld from Hercules between April 1, 1976, and July 31, 1976 pursuant to Ordering Clause B of the Commission's April 1, 1976 Order."

⁸Hercules, Inc. v. FPC, 552 F.2d 74, 89 (3 Cir. 1977).

⁹Ibid.

¹⁰Order Granting Rehearing, Docket No. RP71-119, RP74-31-22, March 8, 1977.

¹¹Docket No. RP73-31-24. A-H had filed a previous petition on March 4, 1974, in Docket No. RP73-31-20. A hearing in that docket was held on May 30, 1974, and the Commission approved a settlement in an order issued July 22, 1974, 52 FPC 199.

¹This proceeding was commenced before the Federal Power Commission (FPC). By the joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the FERC. The term "Commission", when used in the context of action taken prior to October 1, 1977, refers to the FPC; when used otherwise, the reference is to the FERC.

²Docket No. RP73-31-22.

³Initial Decision by Presiding Administrative Law Judge Liebman, dated July 30, 1975, 54 FPC _____. On March 22, 1976, after Opinion No. 754 issued, Panhandle reduced temporary relief deliveries to Hercu-

in its Winchester, Indiana glass plant. The Commission set the petition for hearing and granted A-H temporary relief subject to payback.¹²

The initial decision by Administrative Law Judge Michel Levant reclassified 290 Mcf/d into priority 2 as extraordinary relief.¹³ All temporary and permanent relief gas was ordered to be paid back. This initial decision relied upon the reasoning of Judge Zimmet, which rejected the firm interruptible distinction in Panhandle's curtailment plan.¹⁴

On August 31, 1976, the Commission dismissed A-H's petition for extraordinary relief as moot and ordered payback of outstanding extraordinary relief volumes. Of the 47,072 Mcf of extraordinary relief provided, A-H claims to have repaid 43,293 Mcf.

C. THE CONSOLIDATED PARTIES

The Commission consolidated for hearing a number of extraordinary relief petitions which were filed by eleven Panhandle customers.¹⁵ The initial decision of Administrative Law Judge William Ellis granted extraordinary relief to four of the nine petitioners which remained in the proceeding, subject to payback of only those volumes "utilized in any manner other than that specified in the grant. . . ."¹⁶

The Commission's order of March 8, 1977,¹⁷ commented favorably upon extending the payback obligation to include all relief volumes. However, the Commission did not order payback in light of the Third Circuit decision. As a result none of the consolidated parties ever paid back any extraordinary relief gas, unlike the similarly situated petitioners.

¹² Order issued January 24, 1975.

¹³ Initial Decision issued September 24, 1975, 54 F.P.C.—. This temporary relief was granted to give A-H an opportunity to convert its feeders and lehrs to oil.

¹⁴ *Panhandle Eastern Pipe Line Company*, Docket No. RP71-119, Initial Decision issued August 29, 1975, 54 F.P.C.—.

¹⁵ *Panhandle Eastern Pipeline Company*, Docket Nos. RP71-119, *et al.* order issued December 14, 1973. The parties ultimately consolidated were: Southeastern Michigan Gas Company, Docket RP74-31-1; E. I. Du Pont de Nemours and Company, Docket No. RP74-31-2; Missouri Refractories, Docket No. RP74-31-4; Central Illinois Service Company, Docket No. RP74-31-5; Marblehead Lime Company, Docket No. RP74-31-7; Village of Morton, Illinois, Docket No. RP74-31-10; Mueller Brass Company, Docket No. RP74-31-11; Battle Creek Gas Company and the City of Battle Creek, Michigan, Docket No. RP74-31-13; Anderson Clayton & Co., Docket No. RP74-31-15; City of Monroe City, Missouri, Docket No. RP74-31-16; and Hayes-Albion Corp., Docket No. RP74-31-17.

¹⁶ Initial Decision issued December 30, 1974, Docket RP74-31-1, *et al.* mimeo at 67-68, 52 F.P.C.—.

¹⁷ Order Affirming in Part and Modifying in Part Administrative Law Judges' Initial Decision, issued March 8, 1977.

D. QUANEX

Quanex is also an interruptible Panhandle customer which sought extraordinary relief from the 467-B plan. Quanex uses natural gas in the manufacture of cold-drawn seamless steel tubing.¹⁸ The Commission granted Quanex temporary relief subject to payback.¹⁹ On August 31, 1976, the Commission dismissed the Quanex petition as moot in light of Panhandle's new curtailment plan but continued the payback obligation.²⁰

After the Third Circuit's decision, Quanex petitioned for relief from its payback obligations and for the return of the gas already paid back to Panhandle.

The Commission granted the Quanex petition, and ordered Panhandle to return the extraordinary relief gas which Quanex had paid back.²¹ The amount of gas returned was limited to the amount that Quanex would have received if the Opinion No. 754 plan had been in effect. As a result, of the 165,872 Mcf of extraordinary relief gas received and paid back by Quanex since 1974, 153,859 Mcf was to be added to the Quanex curtailment allocation during the course of a twelve month restitution period.²²

In sum, of the interruptible process use customers: four never were required to repay their relief gas, one had all payback volumes returned, and the two petitioners A-H & Hercules have partially repaid their relief volumes. The latter two companies, through their petitions herein, seek a return of the volumes they have paid back. Providing a return of their payback volumes would accord A-H and Hercules treatment similar to that afforded other Panhandle interruptible customers in similar circumstances.

THE PRESENT PETITIONS

Both the Hercules and A-H petitions rely upon our order in *Quanex* to justify the return of the paid back gas. Both assert that the exact size of the payback volumes will not be disputed. Both would have us order Panhandle to file a statement of account showing the extraordinary relief received, amount paid back and amount which would have been received if the Opinion No. 754 plan had been in effect during the period.

The Hercules and A-H petitions differ in two respects: (1) the amount

¹⁸ The present Panhandle curtailment plan assigns Category 2 curtailment priority to Quanex.

¹⁹ Order issued January 14, 1974, Docket No. RP71-119.

²⁰ Order issued August 31, 1976, Docket No. RP71-119.

²¹ Order issued December 14, 1977, Docket No. TC78-2.

²² Letter from J. T. Kennedy, Vice President, Panhandle Eastern Pipe Line Company, January 11, 1978, filed in Docket No. TC78-2.

of the volumes to be returned and (2) the suggested repayment period. The volumes of gas which A-H seeks returned is one-fourth the volume at issue in *Quanex*, while Hercules requests return of a volume of gas seven times greater than the volume ordered returned in *Quanex*. As a result, the A-H petition requests that the gas be delivered over a 12 month period, while Hercules suggest a 24 month repayment period.

In view of the similarity of issues raised by the two petitions, we are consolidating both dockets and addressing both in a single order.

No one has filed a petition to intervene in Docket No. TC-78-34.²³ General Motors Corporation (GM) has filed a timely petition for leave to intervene in Docket No. RP74-31-24.²⁴ No other notice of intervention, protest or petition to intervene has been filed. GM opposes the return of the gas which A-H has already paid back, but GM does not request a hearing on the A-H petition. GM asks that if we decide to grant relief to A-H, we make clear that the basis for our decision was an exercise of administrative discretion prompted by equitable consideration, and not required by the *Hercules, Inc. v. FPC* decision. We agree.

DISCUSSION

We order the return of payback volumes only as a last resort in our efforts to accord equal treatment to Panhandle customers. However, an application of the following policy considerations and legal principles to less compelling facts would not justify this exceptional remedy.

Payback obligations serve important public interests, which are weakened if payback orders are not ultimately enforced. As we have previously noted, a payback provision "deters exploitation of extraordinary relief, prevents undue advantage going to the recipient of relief, and partially restores volumes, taken from other customers."²⁵ And as Justice Clark observed, "Not only does 'common sense' as the Fifth Circuit states . . . support a payback but common honesty commands it."²⁶ In the absence of compelling equitable considerations, as exist in this case, these policies would dictate that payback volumes not be returned at the expense of other pipeline customers.

²³ Notice of Hercules' petition was published in the FEDERAL REGISTER on August 21, 1978, 43 FR 37001.

²⁴ Notice of this petition was published in the FEDERAL REGISTER on June 12, 1978, 43 FR 25378.

²⁵ *Texas Eastern Transmission Corporation (Carnegie Natural Gas Company)*, Opinion No. 716, Docket No. RP74-39-3, December 16, 1974, 52 FPC 1814 at 1822.

²⁶ *United States Steel Corp. v. FPC*, 175 App. DC 82, 88-89, 533 F.2d 1217, 1223-24, (D.C. Cir., 1976).

Additionally, we feel finality of agency decisions is important, especially in the context of pipeline curtailments. For example, a distinct possibility exists in times of a supply shortage that the delayed restitution of volumes allocated under interim plans ultimately found to be unjust and unreasonable could hinder otherwise available essential service. Similarly, given the recent trend of price increases in both natural gas and alternative fuels, restitution measured in volumes of gas may leave the restored party unjustly enriched, as well as provide a powerful incentive for parties with payback obligations to challenge the underlying curtailment plans in the courts.

A blind application of the doctrine of *res judicata* would also bar Hercules from return of its payback gas. Hercules requested the Court to direct a return of the gas,²⁷ but the Court declined to order such restitution. The current Hercules petition seeks precisely the relief which the Third Circuit has previously declined to provide.

On the facts presented here, however, we are compelled to conclude that equity overrides these concerns. The Third Circuit decision froze the extraordinary relief recipients at disparate stages of repayment. Only by returning the gas paid back will we place the petitioners on an equal footing with the consolidated parties and Qualex.

We emphasize that this remedy is appropriate for the unique sequence of events occurring in the Panhandle curtailment proceeding. It was one of the FPC's earliest attempts at balancing the complex policy concerns posed by "end-use" curtailment. In addition, the FPC's asynchronous processing of petitions for extraordinary relief from Panhandle's old plan resulted in assignments to different administrative law judges and payback orders issuing with varying effective dates. Return of payback gas here should not be viewed as a precedent to be applied to payback obligations incurred on other pipeline systems.

REDELIVERY TERMS

Following the reasoning of our decision in *Qualex*, upon which both A-H and Hercules heavily rely,²⁸ this order does not require that either A-H or Hercules be compensated for any gas it may have received and paid back in excess of what it would have received under the Opinion No. 754 plan. Following our procedure in *Qualex*, we will require Panhandle to file with the Commission a statement for each petitioner showing:

²⁷ Note 7, *supra*.

²⁸ *Panhandle Eastern Pipeline Company (Qualex)*, Docket No. TC 78-2, Order issued December 14, 1977, at 7-8.

(1) The volume of gas the petitioner received in the form of extraordinary relief during each month it received such relief;

(2) The volume of gas the petitioner paid back during each month it paid back gas received as extraordinary relief;

(3) The extent, if any, that volumes delivered to the petitioner, during months when extraordinary relief was received, exceeded the amounts of gas the petitioner would have been entitled to receive if the interim curtailment plan presented in Opinion No. 754 had been in effect.

Again, following our procedure in *Qualex*, since the extraordinary relief volumes granted to A-H and Hercules were to satisfy Priority 3 uses under the 467-B plan, which uses are now Priority 2 under Opinion No. 754, any gas returned to either A-H or Hercules pursuant to this order shall be for Priority 2 uses only. Hence, neither these returned volumes, nor gas which would have been directed to the petitioner's process uses but for the delivery of these returned volumes, shall be used in any priority lower than priority 2.

The improved supply projections contained in Panhandle's September 28, 1978, Form 16 filings indicated sufficient gas to accommodate the return of payback volumes. The volumes to be returned will be less than 0.2% of Panhandle's projected supply for the next twelve months.

To provide A-H and Hercules the maximum flexibility in utilizing the return gas, Panhandle shall deliver this gas, in addition to entitlements under the Opinion No. 754 plan, as needed during the 24 months following the date this order issues.

The Commission finds:

(1) It is in the public interest and consistent with the purposes of the Natural Gas Act to grant A-H and Hercules the relief requested, to the extent indicated in the text of this opinion, and as hereinafter ordered.

(2) Good cause exists to consolidate these proceedings.

(3) Participation by the petitioner to intervene may be in the public interest.

The Commissioner orders:

(A) The petitions for relief filed by A-H and Hercules are granted to the extent indicated above, provided that none of Panhandle's deliveries to A-H and Hercules are used in a priority lower than priority 2 of the Opinion No. 754 curtailment plan.

(B) Panhandle shall file, within sixty days from the date of this order, statements of A-H's and Hercules' accounts as described above.

(C) Docket No. TC78-34 is hereby consolidated with Docket No. RP74-31-24.

(D) GM's petition to intervene is granted subject to the rules and regulations of the Commission: *Provided, however*, that participation shall be limited to matters affecting asserted rights and interests as specifically set forth in the petition to intervene: *Provided, further*, that the admission of such intervenor shall not be construed as recognition by the Commission that it might be aggrieved because of any order of the Commission entered in this proceeding.

By the Commission.

LOIS D. CASHELL,
Acting Secretary.

[FR Doc. 78-35600 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

SOUTHERN NATURAL GAS CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Southern Natural Gas Company (Southern) on December 1, 1978 tendered for filing proposed changes to its FERC Gas Tariff, Volume No. 1. The proposed change consists of Third Revised Sheet No. 45E.

Southern states that the proposed changes are in compliance with FERC Order No. 13 issued October 18, 1978 in Docket No. R-406 providing that carrying charges pursuant to Southern's effective PGA clause on amounts in Account No. 191 shall be exclusive of accrued interest and shall give effect to the principal of interperiod tax allocation in connection with the balances recorded in the unrecovered purchase gas cost account.

Copies of the filing was served upon the companies jurisdictional customers and interested state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make

the protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35619 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

TENNESSEE GAS PIPELINE CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that on December 1, 1978 Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), tendered for filing Third Revised Sheet Nos. 213 and 213C to Ninth Revised Volume No. 1 of its FERC Gas Tariff. Tennessee states that the purpose of the revised tariff sheets, which are to become effective on January 1, 1979, is to revise the PGA clause in Article XXIII of the General Terms and Conditions of its tariff to conform to the requirements of Order No. 13.

Tennessee states that copies of the filing have been mailed to all its jurisdictional customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35620 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket Nos. RP73-114 (PGA79-1), RP74-24 (DCA79-1), RP74-73 (RPD79-1) and RM77-14]

TENNESSEE GAS PIPELINE CO., A DIVISION OF TENNECO, INC.

Proposed Rate Change Under Tariff Rate Adjustment Provisions

DECEMBER 13, 1978.

Take notice that on November 16, 1978, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), tendered for filing Twenty-Third Revised Sheet Nos. 12A and 12B to Ninth Revised Volume No. 1 of its FERC Gas Tariff to be effective on January 1, 1979.

Tennessee states that the purpose of the revised tariff sheets is to adjust Tennessee's rates pursuant to Articles XXIII, XXIV, XXV and XXVII of the General Terms and Conditions of its FERC Gas Tariff, consisting of a PGA rate adjustment, a rate adjustment to reflect curtailment demand charge credits, an R&D adjustment, and a GRI rate adjustment.

Tennessee states that copies of the filing have been mailed to all its jurisdictional customers and affected state regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35601 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket Nos. RP73-114 (PGA79-1a)]

TENNESSEE GAS PIPELINE CO., A DIVISION OF TENNECO, INC.

PGA Rate Increase

DECEMBER 13, 1978.

Take notice that on November 30, 1978, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), tendered for filing Substitute

Twenty-Third Revised Sheet Nos. 12A and 12B to Ninth Revised Volume No. 1 of its FERC Gas Tariff to be effective on January 1, 1979.

Tennessee states that the purpose of the revised tariff sheets is to revise its November 16, 1978 filing in these dockets to reflect the prices resulting from the Natural Gas Policy Act of 1978 and the Commission's Regulations thereunder. Tennessee states that in all other respects the instant filing reflects the same rate adjustments as were reflected in the November 16, 1978 filing.

Tennessee states that copies of the filing have been mailed to all of its jurisdictional customers and affected State regulatory commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene; provided, however, that any person who has previously filed a petition to intervene in this proceeding is not required to file a further petition. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35602 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

TEXAS EASTERN TRANSMISSION CORP.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Texas Eastern Transmission Corporation on December 1, 1978, tendered for filing as part of its FERC Gas Tariff, Fourth Revised Volume No. 1, the following sheets:

Second Revised Sheet No. 102
Second Revised Sheet No. 102A
First Revised Sheet No. 106
First Revised Sheet No. 107
First Revised Sheet No. 108
First Revised Sheet No. 109
First Revised Sheet No. 110
First Revised Sheet No. 111
Third Revised Sheet No. 112
First Revised Sheet No. 113

These revised sheets are being issued pursuant to the Commission's Order

No. 13 issued October 18, 1978 in Docket No. R-406. Texas Eastern submits that the revisions reflected on the above listed tariff sheets are in full compliance with the Commission's requirements for such PGA clause as prescribed in Order No. 13 and as modified by Order No. 13-A issued November 27, 1978.

The above tariff sheets designated as Second Revised Sheet Nos. 102 and 102A are being revised for the sole purpose of conforming the effective dates for filings under Texas Eastern's PGA provision with Texas Eastern's PGA clause as prescribed in Order No. 13.

The proposed effective date of the above tariff sheets is January 1, 1979.

Copies of the filing were served upon the company's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35621 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP79-117]

TEXAS SEA RIM PIPELINE, INC.

Petition for Declaratory Order

DECEMBER 14, 1978.

Take notice that on December 11, 1978, Texas Sea Rim Pipeline, Inc. (Petitioner), P.O. Box 1521, Houston, Texas 77001, filed in Docket No. CP79-117 a petition pursuant to Section 1.7(c) of the Commission's Rules of Practice and Procedure (18 CFR 1.7(c)) for a declaratory order finding that (1) Petitioner is an intrastate pipeline within the meaning of Section 2(16) of the Natural Gas Policy Act of 1978 (NGPA) and (2) the natural gas transportation service proposed by Petitioner for Natural Gas Pipeline Company of America (Natural) would be a non-jurisdictional transportation service under Section 311(a)(2) of the NGPA, all as more fully set forth in

the petition on file with the Commission and open to public inspection.

Petitioner states that it is a wholly-owned subsidiary of The Superior Oil Company (Superior) and would own and operate pipeline facilities connecting an offshore platform in State Tract 14-L, Jefferson County, Texas, with a condensate reseparation facility approximately three miles west of Sabin Pass, Texas. Petitioner indicates that Superior has contracted with Natural for the sale of Superior's portion of the production from the Block 14-L platform and has pending before the Commission in Docket No. CI78-1030 an application for a certificate authorizing such sale and the construction of approximately 15 miles of pipeline from the platform to the reseparation plant. It is asserted that these facilities would be used to transport only gas sold in interstate commerce for resale and would be owned and operated by Petitioner.

The petition indicates further that the State of Texas (Texas) has elected to take its royalty gas in kind and that it has contracted with an intrastate pipeline, United Texas Transmission Company (UTTCO), for the sale of this gas in intrastate commerce. Petitioner states that it would own and operate pipeline facilities, separate and apart from those which are the subject of the application in Docket No. CI78-1030, which facilities would also connect the Block 14-L platform to the reseparation plant and that, upon completion, which is anticipated to be by December 31, 1978, Petitioner would operate such facilities as an intrastate pipeline.

It is asserted that production from the Block 14-L platform is now scheduled to commence on or about January 1, 1979; however, all of the facilities necessary to accomplish the subject transportation arrangements are not in place and cannot be in place by January 1, 1979. Thus, petitioner states that even though its intrastate facility would be operational by January 1, 1979, Texas' gas cannot be transported to its intrastate purchaser, UTTCO. It is indicated that because of this short-term inability to deliver its share of gas from the Block 14-L platform, Texas has entered into a balancing agreement with Superior under which all of the gas produced from the platform would be attributed to Superior's interest, pending completion of the onshore facilities necessary for delivery to UTTCO. However, no interstate facilities are currently available for the transportation of these volumes to Natural's facilities and the only facilities that would be available to transport the additional Block 14-L production for Natural are Petitioner's facilities designed to transport Texas' royalty gas to the intrastate market.

Accordingly, Petitioner proposes to transport said gas for Natural to the latter's existing onshore system, provided Petitioner is assured that such transportation would not subject its facilities designed for intrastate use to the Commission's jurisdiction.

Any person desiring to be heard or to make any protest with reference to said petition should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35603 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

TRANSCONTINENTAL GAS PIPE LINE CORP.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Transcontinental Gas Pipe Line Corporation (Transco) on December 1, 1978, tendered for filing First Revised Sheet No. 247 and Second Revised Sheet Nos. 245 and 249 to its FERC Gas Tariff, Second Revised Volume No. 1 to become effective January 1, 1979.

Transco states that the purpose of the filing is to revise Transco's FERC Gas Tariff in order to comply with the requirements prescribed in Commission Order No. 13 issued October 28, 1978 in Docket No. R-406. Sheet No. 247 reflects the prescribed tracking dates of March 1 and September 1 under Transco's Purchase Gas Adjustment (PGA) clause and Sheet No. 249 provides for the principles of interperiod income tax allocation in the determination of carrying charges on balances in FERC Account No. 191—Unrecovered Purchased Gas Cost Account. Sheet No. 245 is being filed to provide that any rate adjustments to be made effective subsequent to February 1, 1979 to "track" curtailment-related credits shall become effective on the same dates as changes in rates under Transco's PGA clause. Pursuant to the Settlement Agreement approved by the Commission in Trans-

co's Docket Nos. RP76-136 and RP77-26, Transco made a one-time rate adjustment in Docket Nos. RP76-136 and RP77-26, RP72-99 (DCA No. 78-3) to be effective for the period August 1, 1978 through January 31, 1979 in connection with the approved switch from a deferred method of recovery of curtailment-related credits to a current method of recovery. Therefore, Transco states that it will file a rate reduction to be effective February 1, 1979 to reflect the termination of this one-time rate adjustment.

The Company states that copies of the filing have been mailed to each of its jurisdictional customers and interested State Commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35623 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

TRANSWESTERN PIPELINE CO.

Proposed Amendments to Purchased Gas Cost Adjustment Provisions

DECEMBER 11, 1978.

Take notice that Transwestern Pipeline Company (Transwestern) on December 1, 1978, tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following sheets:

Revised Second Revised Sheet No. 74
First Revised Sheet No. 75
Second Revised Sheet No. 76

These revised sheets are being issued pursuant to the Commission's Order No. 13 issued October 18, 1978 in Docket No. R-406. Transwestern submits that the revisions reflected on the above listed tariff sheets are in full compliance with the Commission's requirements for such PGA clause as prescribed in Order No. 13 and as modified by Order No. 13-A issued November 27, 1978.

The proposed effective date of these tariff sheets is January 1, 1979.

Copies of the filing were served upon the company's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 22, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35622 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. RP73-94 (PGA79-1)]

VALLEY GAS TRANSMISSION, INC.

PGA Rate Increase

DECEMBER 13, 1978.

Take notice that on December 1, 1978, Valley Gas Transmission, Inc. ("Valley"), submitted for filing as part of its FERC Gas Tariff, Original Volume No. 1, its proposed "Fourteenth Revised Sheet No. 2A". The proposed effective date is January 1, 1979.

Valley states that this tariff sheet is filed pursuant to its currently effective Purchased Gas Cost Adjustment Provision. The proposed changes involve Valley's "Current Surcharge Adjustment" and "Current Gas Cost Adjustment." The adjustments are supported by computations attached to the filing.

Valley also requests waiver of the provisions of its currently effective PGA clause so that it may recover the amounts in its Deferred Account in the four-month period January through April, 1979, rather than the six-month period January through June, 1979, which would normally be used. Valley asserts that this proposal is consistent with the change required in its PGA clause by Order Nos. 13 and 13-A which will shorten the effective time period of the proposed rates from six months under the currently effective PGA clause to four months under the new clause.

Any person desiring to be heard or to protest said application should file

a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceedings. Any person wishing to become a party must file a petition to intervene. Copies of the filing are on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35604 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. R-406]

VALLEY GAS TRANSMISSION, INC.

Proposed Changes to FERC Gas Tariff

DECEMBER 13, 1978.

Valley Gas Transmission, Inc. ("Valley"), on December 1, 1978, submitted for filing as part of its FERC Gas Tariff, Original Volume No. 1, the following tariff sheets:

First Revised Sheet No. 177
First Revised Sheet No. 178
First Revised Sheet No. 179
First Revised Sheet No. 180
Original Sheet No. 180A
Original Sheet No. 180B

Valley states that these tariff sheets comply with the requirements of the Commission's Order Nos. 13 and 13-A by changing the dates on which Valley will file its future PGA adjustments and by providing for carrying charges on the balances in the Deferred Account.

The proposed effective date is January 1, 1979.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene. Copies of the filing are on file with the Commission.

sion and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35624 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket Nos. RP74-85 and R-406]

WESTERN GAS INTERSTATE CO.

Proposed Changes to FERC Gas Tariff

DECEMBER 13, 1978.

Western Gas Interstate Company ("Western"), on December 1, 1978, submitted for filing as part of its FERC Gas Tariff the following tariff sheets:

Original Volume No. 1—

Eleventh Revised Sheet No. 3A
Second Revised Sheet No. 33
Second Revised Sheet No. 33A
Second Revised Sheet No. 33B
Third Revised Sheet No. 33C

Western states that these tariff sheets, *inter alia*, comply with the requirements of the Commission's Order Nos. 13 and 13-A by changing the dates on which Western will file its future PGA adjustments and by providing for carrying charges on the balances in the Deferred Account.

In addition, Western states that it has made other changes to its PGA clause to reflect certain editorial changes, revisions in the Commission's Regulations promulgated by Order No. 15, and the addition of Rate Schedule G-R applicable to a newly certificated service.

The proposed effective date is January 1, 1979.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426 in accordance with the Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedures (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene. Copies of the filing are on file with the Commission and available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35625 Filed 12-21-78; 8:45 am]

[6740-02-M]

Federal Energy Regulatory Commission

[Docket No. CP76-506]

COLUMBIA GAS TRANSMISSION CORP.

Petition To Amend

DECEMBER 12, 1978.

Take notice that on October 30, 1978, Columbia Gas Transmission Corporation (Columbia), 1700 Mac CORKle Avenue SE., Charleston, West Virginia 25314, filed in Docket No. CP76-506,¹ a petition to amend the order issued November 24, 1976, in said docket, pursuant to Section 7(c) of the Natural Gas Act and Section 2.79 of the Commission's General Policy and Interpretations (18 CFR 2.79) so as to extend for two years the authorization to transport natural gas for Diamond Shamrock Corporation (Diamond), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

It is stated that service pursuant to the order of November 24, 1976, commenced November 30, 1976. By an assignment and assumption agreement, dated May 26, 1978, Diamond assigned all of its rights and delegated all of its duties contained in the gas transportation agreement between Columbia and Diamond, dated July 22, 1976, to Chemetals Corporation, it is said. Columbia consented to such assignment and delegation and by Petition filed June 8, 1978, requested the Commission to issue an amendment to the certificate of public convenience and necessity issued herein on November 24, 1976, authorizing the transportation of natural gas for Chemetals, it is said.

It is stated that the gas transportation agreement between Columbia and Chemetals, by virtue of assignment, was for a term of two years and thereafter on a year to year basis. Chemetals has requested that Columbia extend the transportation service for an additional two-year term and Columbia has agreed to this request, it is said.

It is stated that the gas to be transported would be purchased by Chemetals from Diamond from wells located in Lipscomb County, Texas, at a cost of \$1.75 per Mcf. Gas with a heating value of more or less than 1,000 Btu per cubic foot would result in either an increase or decrease in price, it is said. Columbia would receive the gas at an existing point of delivery located in Lucas County, Ohio from Panhandle Eastern Pipe Line Company, transport and deliver such gas on an inter-

¹This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 100.1), it was transferred to the FERC.

ruptible basis to Baltimore Gas and Electric Company (BG&E), for the account of Chemetals, it is said. By letter dated July 3, 1978, BG&E has indicated that Chemetals would be forced to shut down if replacement gas presently available to them is not renewed or delivered, it is said.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to the proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35591 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP77-40]

EL PASO NATURAL GAS CO.

Amendment

DECEMBER 11, 1978.

Take notice that on November 7, 1978, El Paso Natural Gas Company (El Paso), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP77-40 an amendment to its pending application for a certificate of public convenience and necessity, pursuant to Section 7(c) of the Natural Gas Act so as to provide for the establishment of a new delivery point between El Paso and The Energy and Minerals Department of the State of New Mexico (EMD), all as more fully set forth in the amendment which is on file with the Commission and open to public inspection.

El Paso states that on October 26, 1976,¹ it filed an application with the Commission for a certificate of public convenience and necessity authorizing the transportation and delivery by El Paso of up to 10,000 Mcf per day of natural gas in interstate commerce, for the account of the EMD, to certain gas distributors designated by the EMD at various existing points of de-

¹This proceeding was commenced before the FPC. By joint resolution of October 1, 1977 (10 CFR 1000.1), it was transferred to the FERC.

livery located on El Paso's interstate pipeline system within the State of New Mexico, pursuant to a gas transportation agreement dated July 16, 1976, between El Paso and the EMD.

El Paso further states that the subject natural gas constitutes royalty gas purchased by the EMD from the Commissioner of Public Lands of the State of New Mexico from certain wells located within that state and that the quantities of natural gas proposed to be transported and delivered are sold by the EMD to designated gas distributors pursuant to supplemental gas sales agreements between the EMD and the distributors, individually. In addition, El Paso requested budget-type authorization in Docket No. CP77-40 to permit, from time to time, the attachment to El Paso's pipeline system of future supplies of natural gas for transportation in accordance with the transportation agreement, it is said.

The EMD has informed El Paso that it has entered into a supplemental gas sales agreement dated July 18, 1978, with the City of Socorro, New Mexico (City of Socorro), providing for the sale by the EMD and purchase by the City of Socorro of supplemental natural gas supplies, which the EMD desires El Paso to transport through El Paso's interstate pipeline system for resale and ultimate consumption of the City of Socorro's authorized New Mexico service area, it is stated. The term of the supplemental gas sales agreement is for three years commencing on the date of first deliveries, and year-to-year thereafter subject to termination by either the EMD or the City of Socorro upon due notice to the other party, it is said.

Therefore, El Paso states that it hereby amends its application filed October 26, 1976, to request authorization for the City of Socorro as a new delivery point.

El Paso states further that it and the EMD have executed a revised Exhibit B to the transportation agreement to reflect the proposed additional delivery point necessary for the delivery of natural gas by El Paso to the City of Socorro for the account of the EMD. El Paso states it has constructed and now operates, as a part of its interstate pipeline system, tap, regulating and metering facilities necessary to deliver natural gas to the City of Socorro, and it intends to utilize such facilities for the proposed delivery of natural gas to the City of Socorro for the EMD's account. It is further asserted that as set forth in the supplemental gas sales agreement dated July 18, 1978, between the EMD and the City of Socorro, El Paso would deliver up to 300 Mcf of natural gas per day to the City of Socorro for the account of the EMD.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken, but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35592 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket Nos. CI77-145, CI77-148 and CI77-192]

FREEPORT OIL CO.

Petition To Amend Certificates of Public Convenience and Necessity and Redesignate Rate Schedules

DECEMBER 13, 1978.

Take notice that on June 28, 1978, Freeport Oil Company (Freeport) P.O. Box 3038, Midland, Texas 79702, filed in Docket Nos. CI77-145, CI77-148 and CI77-192, a petition to amend certificates of public convenience and redesignate rate schedules, which such certificates and such rate schedules are in the name of either Freeport Minerals Company (Freeport Minerals) or Freeport Oil Company, a division of Freeport Minerals (Freeport Division), to show that Freeport Oil Company, a Delaware corporation, as certificate holder.

Effective November 1, 1977, Freeport Minerals incorporated Freeport as a wholly-owned subsidiary and caused to be assigned to Freeport all of the properties covered by the rate schedules from which Freeport Minerals and Freeport Division were making sales of gas as a result of a corporate restructuring.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 10 days for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard or to make any protest with reference to said application should on or before December 22, 1978, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to

intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35593 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. RP76-148 (PGA79-1)]

GAS GATHERING CORP.

Corrected Proposed Change in Rates Under Purchased Gas Adjustment Clause Provision

DECEMBER 13, 1978.

Take notice that Gas Gathering Corporation (GGC), on November 10, 1978, tendered for filing proposed changes in its F.E.R.C. Gas Tariff providing for increased charges to Transcontinental Gas Pipe Line Corporation (Transco), its sole jurisdictional customer, under GGC's PGA clause. The proposed changes would increase the rate charged Transco by 51.84007 cents per Mcf over those rates presently in effect. The proposed rates are proposed to be made effective on January 1, 1979. GGC states that the filing is made to allow it to recover increased current costs of purchased gas, and to permit it to recover the balance of its Unrecovered Purchased Gas Cost Account as of September 30, 1978 through a six-month surcharge.

Since the time of its filing of November 10, 1978, GGC states that it has been informed by Amoco Production Company that deliveries to GGC under Rate Schedule No. 560, Supplement No. 19, will not qualify for the 156.3862 cents per Mcf price authorized by Letter Order dated August 11, 1978, OPR-832 (3663) Amoco Production Company, effective April 1, 1978, as GGC had previously thought to be the case. Accordingly, GGC submitted a correction to its original filing for the proposed increase to be made effective on January 1, 1979. As so corrected, GGC requests a rate increase of 12.63167 cents per Mcf over those rates presently in effect.

Accordingly, GGC submitted for substitution:

(a) Substitute Exhibit A (Substitute Third Revised Sheet No. 8 of 8, Supplement No. 24 to Rate Schedule No. 2)

(b) Revised Exhibit B, pages 1, 4, 5 and 6 of 6 (A recomputation of the current and surcharge adjustments)

GGC requests that these substitute exhibits be considered as though filed on November 10, 1978, and that the proposed increase as so corrected be made effective under the terms previously requested.

A copy of the filing has been served upon Transco.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 20, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35594 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. RP73-17 (PGA79-1)]

GRANITE STATE GAS TRANSMISSION, INC.

PGA Rate Increase

DECEMBER 13, 1978.

Take notice that Granite State Gas Transmission, Inc. (Granite State), 66 Market Street (P.O. Box 508), Portsmouth, New Hampshire 03801, on November 30, 1978, tendered for filing

Twenty-Fifth Revised Sheet No. 3A in its FERC Gas Tariff, Original Volume No. 1, containing a proposed change in rates for effectiveness on January 1, 1979.

According to Granite State, the instant filing tracks changes in its cost of gas purchased from Tennessee Gas Pipeline Company, a Division of Tenneco, Inc. (Tennessee) which Tennessee has proposed to make effective January 1, 1979, in Docket No. RP73-114, et al. It is stated that Granite State's filing is made pursuant to the purchase gas cost adjustment provision in its tariff, approved on December 14, 1972, in Docket No. RP73-17.

Granite State further states that its revised purchased gas cost change is applicable to its sale to Northern Utilities, Inc. (Northern), which is Granite State's sole jurisdictional customer. According to Granite State, the effect of the proposed rate contained on Twenty-Fifth Revised Sheet No. 3A on Northern's purchases from Granite State is an increase of \$26,186.95 annually, based on purchases from Tennessee and sales to Northern for the twelve months ended October 31, 1978.

According to Granite State, copies of the filing were served upon Northern and the regulatory commissions of the States of Maine and New Hampshire.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 19, 1978. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35595 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP79-93]

LONE STAR GAS CO., A DIVISION OF
ENSERCH CORP.

Application

DECEMBER 12, 1978.

Take notice that on November 28, 1978, Lone Star Gas Company, a Division of Enserch Corporation (Lone Star), 301 South Harwood Street, Dallas, Texas 75201, filed an applica-

tion pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing a proposed exchange of gas between Lone Star and Arkansas Louisiana Gas Company (Arkla), all as more fully set forth in the application on file with the Commission and open for public inspection.

It is stated that, pursuant to two agreements between Lone Star and Arkla, dated August 18, 1978, Arkla agreed to assign to Lone Star 20 percent of its purchase rights in natural gas from certain properties in Panola County, Texas, and further, that Arkla agreed to exchange this gas with Lone Star by receiving for Lone Star's account gas purchased by Lone Star in Panola County, Texas, and then delivering to Lone Star an equal volume of gas at a mutually agreeable point where pipelines of the two companies intersect in McClain County, Oklahoma.

Lone Star states that the Panola County gas is remote from its facilities, but connected with Arkla's. Lone Star proposes no new facilities.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35596 Filed 12-21-78; 8:45 am]

[6740-02-M]

[Docket No. CP79-91]

NORTHERN NATURAL GAS CO.

Application

DECEMBER 12, 1978.

Take notice that on November 29, 1978, Northern Natural Gas Company (Applicant), 2223 Dodge Street, Omaha, Nebraska 68102, filed in Docket No. CP79-91, an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon the transportation and sale of natural gas in interstate commerce to Inter-City Gas Limited, Inc. (Inter-City), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

It is stated that applicant is currently authorized to transport and sell to Inter-City 818 Mcf per day during the period December 15 through March 15 pursuant to its WPS-1 rate schedule and 459 Mcf per day during the period November 27 through March 26 pursuant to its SS-1 rate schedule. It is stated that Inter-City has requested that these contract demands be terminated due to conservation and conversions to alternate fuels by its customers in the market area served by Applicant.

Applicant does not propose to reallocate the volumes being cancelled.

Any person desiring to be heard or to make any protest with reference to said application should on or before January 2, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the

proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this application if no petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

KENNETH F. PLUMB,
Secretary.

[FR Doc. 78-35597 Filed 12-21-78; 8:45 am]

[6450-01-M]

Office of the Secretary

NATIONAL PETROLEUM COUNCIL, TASK GROUP OF THE COMMITTEE ON TIGHT GAS RESERVOIRS

Meeting

Notice is hereby given that the National Petroleum Council, Committee on Unconventional Gas Sources, Tight Gas Reservoirs Task Group will meet on Wednesday, January 3, 1979, starting at 9:00 am in the Conference Room on the 31st floor of the Mobil Oil Corporation, Coastal Building, Greenway Plaza, Southwest Freeway, Edloe Street, Houston, Texas.

The National Petroleum Council was established to provide advice, information, and recommendations to the Secretary of Energy on matters relating to oil and natural gas or the oil and natural gas industries.

The tentative agenda for the meeting follows:

1. Introductory remarks by Chairman and Government.

2. Discussion of the study methodology to be employed by the Tight Gas Reservoirs Group.

3. Discussion of the timetable of the Tight Gas Reservoirs Task Group.

4. Discussion of any other matters pertinent to the overall assignment of the Tight Gas Reservoirs Task Group.

The meetings are open to the public. The Chairmen of the task group are empowered to conduct the meetings in a fashion that will, in their judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the task group will be permitted to so do, either before or after the meeting. Members of the public who wish to make oral statements should inform Lucio D'Andrea, Office of Resource Applications, 202-633-8383, prior to the meeting and reasonable provision will be made for their appearance on the agenda.

Transcripts of the meeting will be available for public review at the Freedom of Information Public Reading Room, Room GA 152, DOE, Forrestal Building, 1000 Independence Avenue, SW, Washington, D.C., between the hours of 8:00 am and 4:30 pm, Monday through Friday, except Federal holidays. Any person may purchase a copy of the transcripts from the reporter.

Issued at Washington, D.C. on December 15, 1978.

GEORGE S. McISAAC,
Assistant Secretary for
Resource Applications.

DECEMBER 15, 1978.

[FR Doc. 78-35590 Filed 12-21-78; 8:45 am]

[6450-01-M]

PEACEFUL USES OF ATOMIC ENERGY

Proposed Subsequent Arrangements

Pursuant to Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed "subsequent arrangement" under the Agreements for Cooperation Between the United States and Austria, European Community, Sweden, Switzerland and the International Atomic Energy Agency (IAEA), for Civil Uses of Atomic Energy.

The Subsequent Arrangements to be carried out under the above named agreements involve the following transfers of U.S.-origin material from the European Community to Austria, Greece, Sweden and Switzerland:

U.S. Export License Number	Countries Involved	End Use	Material
XSNM-1074, Issued June 12, 1978	Germany to Sweden	R-2 research reactor	21.05 kgs of U containing 19.6 kgs of U-235
XSNM-914 (Amendment No. 1), Issued August 3, 1978	Germany to Sweden	Barsemark No. 2	144,800 kgs of U containing 3,000 kgs of U-235
XSNM-1311, Issued August 31, 1978	Germany to Sweden	Barsemark No. 2 power reactor	89,800 kgs of uranium containing 2,739 kgs of U-235

U.S. Export License Number	Countries Involved	End Use	Material
XSNM-1314, Issued August 31, 1978	Germany to Sweden	OKG No. 1 power reactor	52,688 kgs of U containing 1,501 kgs of U-235
XSNM-1278, Issued Sept. 13, 1978	Germany to Sweden	Barsemark No. 1 power reactor	55,440 kgs of U containing 1,664 kgs of U-235
XSNM-1234, Issued Sept. 13, 1978	France to Greece (under the US/IAEA Agreement for Cooperation)	Greek Research Reactor at the Democritus Research Center	7.0 kgs of U containing 6.53 kgs of U-235
XSNM-1306, Issued Sept. 21, 1978	Germany to Sweden	OKG-2 power reactor	17,472 kgs of U containing 568 kgs of U-235
XSNM-891 (Amendment No. 2), Issued Sept. 27, 1978	Germany to Sweden	Ringals No. 2 power reactor	99,860 kgs of U containing 2,846 kgs of U-235
XSNM-1141 (Amendment No. 1), Issued May 19, 1978	Germany to Switzerland	Gosgen reactor	24,545 kgs of uranium containing 823 kgs of U-235
XSNM-916 (Amendment No. 2), Issued April 20, 1978	Germany to Sweden	Ringals Unit No. 1	124,400 kgs of uranium containing 3,480 kgs of U-235
XSNM-95 (Amendment No. 5), Issued Nov. 22, 1978	Germany to Switzerland	Muhleberg reactor	47,009 kgs of U containing 1,120 kgs of U-235

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that these subsequent arrangements will not be inimical to the common defense and security.

These subsequent arrangements will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: December 18, 1978.

HAROLD D. BENIGSDORF,
Director for Nuclear Affairs,
International Programs.

[FR Doc. 78-35589 Filed 12-21-78; 8:45 am]

[6730-01-M]

FEDERAL MARITIME COMMISSION

[Independent Ocean Freight Forwarder
License No. 1886]

OCEAN-AIR FORWARDING, INC.

Order of Revocation

On November 24, 1978, Ocean-Air Forwarding, Inc., R.D. #1, Burgettstown, Pennsylvania 15021, requested the Commission to revoke its Independent Ocean Freight Forwarder License No. 1886.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), section 5.01(c), dated August 8, 1977;

It is ordered, That Independent Ocean Freight Forwarder License No. 1886, issued to Ocean-Air Forwarding, Inc. be and is hereby revoked effective November 24, 1978 without prejudice to reapplication for a license in the future.

It is further ordered, That Independent Ocean Freight Forwarder License No. 1886, issued to Ocean-Air Forwarding, Inc. be returned to this Commission for cancellation.

It is further ordered, That a copy of this Order be published in the FEDERAL

REGISTER and served upon Ocean-Air Forwarding, Inc.

ROBERT G. DREW,
Director, Bureau of
Certification and Licensing.

[FR Doc. 78-35641 Filed 12-21-78; 8:45 am]

[6730-01-M]

[Independent Ocean Freight Forwarder
License No. 2058]

OCEAN AIR FREIGHT & TRADE, INC.

Order of Revocation

On November 30, 1978, Ocean Air Freight & Trade, Inc., 300 Winston Drive, Cliffside Park, New Jersey 07010, voluntarily surrendered its Independent Ocean Freight Forwarder License No. 2058 for revocation.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), section 5.01(c), dated August 8, 1977;

It is ordered, That Independent Ocean Freight Forwarder License No. 2058 issued to Ocean Air Freight & Trade, Inc., be and is hereby revoked effective November 30, 1978, without prejudice to reapplication for a license in the future.

It is further ordered, That a copy of this Order be published in the FEDERAL REGISTER and served upon Ocean Air Freight & Trade, Inc.

ROBERT G. DREW,
Director, Bureau of
Certification and Licensing.

[FR Doc. 78-35642 Filed 12-21-78; 8:45 am]

[6730-01-M]

[Independent Ocean Freight Forwarder
License No. 2038]

PAN OCEAN, INC.

Order of Revocation

On November 29, 1978, Pan Ocean, Inc., 715 W. Anaheim St., Long Beach,

California 90813, voluntarily surrendered its Independent Ocean Freight Forwarder License No. 2038 for revocation.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), section 5.01(c) dated August 8, 1977;

It is ordered, that Independent Ocean Freight Forwarder License No. 2038, issued to Pan Ocean, Inc. be and is hereby revoked effective November 29, 1978 without prejudice to reapplication for a license in the future.

It is further ordered, that a copy of this Order be published in the FEDERAL REGISTER and served upon Pan Ocean, Inc.

ROBERT G. DREW,
Director, Bureau of
Certification and Licensing.

[FR Doc. 78-35639 Filed 12-21-78; 8:45 am]

[6730-01-M]

[Independent Ocean Freight Forwarder
License No. 1847]

WILLIAMS SHIPPING CO., INC.

Order of Revocation

On December 11, 1978, Williams Shipping Company, Inc., 3255 Grace Street, N.W., Washington, D.C. 20007, voluntarily surrendered its Independent Ocean Freight Forwarder License No. 1847 for revocation effective December 1, 1978.

Therefore, by virtue of authority vested in me by the Federal Maritime Commission as set forth in Manual of Orders, Commission Order No. 201.1 (Revised), § 5.01(c), dated August 8, 1977;

It is ordered, That Independent Ocean Freight Forwarder License No. 1847, issued to Williams Shipping Company, Inc. be and is hereby revoked effective December 1, 1978, without prejudice to reapplication for a license in the future.

It is further ordered, That a copy of this Order be published in the FEDERAL

REGISTER and served upon Williams Shipping Company, Inc.

ROBERT G. DREW,
Director, Bureau of
Certification and Licensing.

[FR Doc. 78-35640 Filed 12-21-78; 8:45 am]

[6730-01-M]

PETITION TO ALLOW OFFICERS OR EMPLOYEES OF A RATE-FIXING AGREEMENT TO SERVE AS THE POLICING AUTHORITY

Filing of Petition

Pursuant to § 528.3(b)(3) of Part 528, 46 CFR (General Order 7 Revised) a petition for exemption to allow an agreement employee to perform the self-policing functions in lieu of an independent policing authority has been filed on behalf of the Red Sea and Gulf of Aden/U.S.A. Conference.

Interested parties may inspect and obtain a copy of the petition at the Washington Office of the Federal Maritime Commission, 1100 L Street NW., Room 11101, and at the Field Offices located at New York, New York; New Orleans, Louisiana; San Francisco, California; Chicago, Illinois; and San Juan, Puerto Rico. Comments on the petition may be submitted to the Secretary, Federal Maritime Commission, Washington, D.C. 20573, on or before January 11, 1979. Comments should include facts and arguments concerning the request for an exemption.

By Order of the Federal Maritime Commission.

FRANCIS C. HURNEY,
Secretary.

DECEMBER 19, 1978.

[FR Doc. 78-35637 Filed 12-21-78; 8:45 am]

[6730-01-M]

SECURITY FOR THE PROTECTION OF THE PUBLIC; INDEMNIFICATION OF PASSENGERS FOR NONPERFORMANCE OF TRANSPORTATION

Issuance of Certificate (Performance)

Notice is hereby given that the following has been issued a Certificate of Financial Responsibility for Indemnification of Passengers for Nonperformance of Transportation pursuant to the provisions of Section 3, Public Law 89-777 (80 Stat. 1357, 1358) and Federal Maritime Commission General Order 20, as amended (46 C.F.R. Part 540), which Certificate expires April 15, 1979:

Malone & Hyde, Inc. d/b/a Quality Incentive Company, P.O. Box 18428, 4690 Hungerford Road, Memphis, Tennessee 38118.

Dated: December 19, 1978.

FRANCIS C. HURNEY,
Secretary.

[FR Doc. 78-35638 Filed 12-21-78; 8:45 am]

[1505-01-M]

AGREEMENTS FILED

Correction

In FR Doc. 78-35130 appearing on page 59133 in the issue for Tuesday, December 19, 1978, second column, sixteenth line, the date should read "December 26, 1978".

[6210-01-M]

FEDERAL RESERVE SYSTEM

BANK OF MANSFIELD HOLDING CO.

Formation of Bank Holding Company

Bank of Mansfield Holding Company, Mansfield, Missouri, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 91.5 percent of the voting shares of Bank of Mansfield, Mansfield, Missouri. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of St. Louis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than January 10, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 18, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-35632 Filed 12-21-78; 8:45 am]

[6210-01-M]

DELAWARE SERVICE CO., INC.

Retention and Acquisition of Bank Shares

Delaware Service Co., Inc., Manchester, Iowa, has applied for the Board's approval under Section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to retain 0.3 per cent of the voting shares of First State Bank, Manchester, Iowa ("Bank"), and to ac-

quire 1.75 per cent of the voting shares of Bank. The factors that are considered in acting on the application are set forth in Section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment of the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than January 15, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 15, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-35633 Filed 12-21-78; 8:45 am]

[6210-01-M]

SAC CITY LTD.

Formation of Bank Holding Company

Sac City Limited, Sac City, Iowa, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Sac City State Bank, Sac City, Iowa. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than January 11, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 18, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-35634 Filed 12-21-78; 8:45 am]

[6210-01-M]

THOMSON INVESTMENT COMPANY, INC.**Retention of Bank Shares**

Thomson Investment Company, Inc., Savanna, Illinois, has applied for the Board's approval under Section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to retain 11.2 percent of the voting shares of Thomson State Bank, Thomson, Illinois. The factors that are considered in acting on the application are set forth in Section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, to be received not later than January 15, 1979. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, December 15, 1978.

GRIFFITH L. GARWOOD,
Deputy Secretary of the Board.

[FR Doc. 78-35635 Filed 12-21-78; 8:45 am]

[6820-24-M]

**GENERAL SERVICES
ADMINISTRATION**

[Intervention Notice 76]

**CALIFORNIA PUBLIC UTILITIES COMMISSION,
ENERGY COST ADJUSTMENT MECHANISM****Proposed Intervention-Rate Proceeding**

The Administrator of General Services seeks to intervene in a proceeding before the California Public Utilities Commission involving an investigation of the California Energy Cost Adjustment Mechanism. The Administrator of General Services represents the interests of the executive agencies of the United States Government as users of utility services.

Persons desiring to make inquiries of GSA concerning this case should submit them, in writing, to Mr. Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th & F Streets, NW., Washington, DC 20405, telephone (202) 566-0726, on or before January 22, 1979, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry

shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, (40 U.S.C. 481(a)(4).)

Dated: November 27, 1978.

JAY SOLOMON,
*Administrator of
General Services.*

[FR Doc. 78-35536 Filed 12-21-78; 8:45 am]

[6820-34-M]

TASK FORCE ON HISTORIC PRESERVATION**Establishment of Advisory Committee**

Establishment of Advisory Committee. This notice is published in accordance with the provisions of section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463) and advises of the establishment of a Task Force for review of the policies concerning historic preservation of the General Services Administration (GSA). The Administrator of General Services has determined that this advisory committee is in the public interest.

Designation. Task Force on Historic Preservation.

Purpose. To review existing procedures and make recommendations as appropriate to the Administrator of General Services with respect to the methods by which GSA fulfills its mandate regarding the acquisition and rehabilitation of historic structures. The objective is to utilize the experience and expertise of various segments of the community in conducting the review.

General Information. Pursuant to Office of Management and Budget Circular A-63, the Committee Management Secretariat has authorized a period of less than 15 days between publication of this notice and the filing of the committee charter.

Dated: December 15, 1978.

JAY SOLOMON,
*Administrator of
General Services.*

[FR Doc. 78-35537 Filed 12-21-78; 8:45 am]

[4110-03-M]

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE****Food and Drug Administration**

[Docket No. 78N-0367]

COLONIAL BLOOD COMPONENTS, INC.**Revocation of U.S. License No. 662**

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Commissioner of Food and Drugs revokes the establishment and product license of Colonial Blood Components, Inc., (U.S. License No. 662) to manufacture Source Plasma (Human) because of significant deviations from the biologics regulations.

EFFECTIVE DATE: September 28, 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 (U.S. License No. 662) issued to Colonial Blood Components, Inc., for its three locations at 300 Luckie St., Atlanta, GA 30313; 405 Market St., Chattanooga, TN 37402; and 214 34th St., Newport News, VA 23607, for the manufacture of Source Plasma (Human).

An inspection of the Chattanooga, TN, location from April 25 through May 11, 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 Source Plasma (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))) and the collection of more than the maximum permissible amount of whole blood from donors in a 48-hour period and in a 7-day period (see § 640.65(b)(4) and (5) (21 CFR 640.65(b)(4) and (5))). This inspection resulted in a suspension of the Chattanooga, TN, location on May 15, 1978. The Chattanooga, TN, and Newport News, VA, locations were suspended previously in March, 1977 for failure to notify FDA of changes in manufacturing methods (see § 601.12(b) (21 CFR 601.12(b))) and were reinstated after the deviation was corrected.

An inspection of the Atlanta, GA, location from May 18 through 25, 1978 revealed numerous deviations from the requirements of Part 600, including several instances of plasmapheresing donors more than twice within a 7-day period (see 21 CFR 640.65(b)(5)), and the collection of more than the maximum permissible amount of whole blood from donors at one time (see 21 CFR 640.65(b)(6)). Both of these deviations were observed in an inspection of the same location in September 1977. In addition, other deviations in the May 1978 inspection of the Atlanta, GA, location were also ob-

served in the April-May 1978 inspection of the Chattanooga, TN, location.

As a result of the May 1978 inspection of the Atlanta, GA, location and under § 601.6(a) (21 CFR 601.6(a)), the agency notified Colonial Blood Components, Inc., in a letter dated May 31, 1978, that the pattern of noncompliance is evidence of the firm's lack of control and supervision in all matters relating to compliance with the regulations and suspended the firm's licenses for the Atlanta, GA, and Newport News, VA, locations.

After the May 1978 suspensions and before further regulatory action was taken, the firm requested that its establishment and product license be revoked and has waived the opportunity for a hearing under § 601.5(a) (21 CFR 601.5(a)). The agency has granted 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) and redelivered to the Director of the Bureau of Biologics (21 CFR 5.68), U.S. License No. 662 issued to Colonial Blood Components, Inc., and the firm's product license for the manufacture of Source Plasma (Human), were revoked by a letter dated September 28, 1978. This notice of revocation is published under § 601.8 (21 CFR 601.8).

Dated: December 18, 1978.

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

[FR Doc. 78-35586 Filed 12-21-78; 8:45 am]

[4110-03-M]

[Docket No. 78D-0405]

EXEMPTION FROM CERTAIN MICROWAVE OVEN LABELING

Availability of Petition Guideline

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces the availability of "Guidelines for Exemption From the Microwave Oven Labeling Requirements of 21 CFR 1030.10(c)(6)(i)," which has been developed to aid microwave oven manufacturers in preparing petitions for exemption from labeling requirements of the radiation safety performance standards. The guideline also contains a summary of the basis for the tests and criteria, and the rationale for each of the substantive provisions. This notice also reviews the procedures used for the development of the guidelines. Although issued in final form, these guidelines may be subject to revision on the basis of scientific and technical information not previously

considered, and the agency invites interested persons to submit pertinent information, data, and comments. Revisions will be developed in a manner similar to that used for preparation of the original guidelines.

DATE: After June 20, 1979, exemptions are to be based on criteria contained in the guidelines or their equivalent. Comments submitted by March 22, 1979, will be considered in the preparation of appropriate revisions.

ADDRESS: Comments should be submitted to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Copies of the guideline are available from the Bureau of Radiological Health (HFX-430), 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Albert Van De Griek, Bureau of Radiological Health (HFX-430), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6540.

SUPPLEMENTARY INFORMATION:

In the FEDERAL REGISTER of April 2, 1975 (40 FR 14750), the Commissioner of Food and Drugs amended the performance standard for microwave ovens (§ 1030.10 (21 CFR 1030.10)). Section 1030.10(c)(6)(i) of the standard requires that a warning label, intended primarily for oven users, be attached to the ovens. Section 1030.10(c)(6)(iv) provides for an exemption from or more of the label warning statements upon application to, and approval by, the Director, Bureau of Radiological Health. In the preamble to the April 1975 amendment, the Commissioner stated that the exemption would be granted if an evaluation of the application, based on certain criteria, were to show a very low probability of occurrence of the radiation exposure situation for which the exemption is sought. The Director of the Bureau of Radiological Health has received several applications from manufacturers for exemption from the labeling requirements. Consideration of these applications indicates that guidelines would be helpful to manufacturers and the Bureau to aid in the preparation and evaluation of such applications.

The Commissioner believes that more definitive guidance on tests and criteria to be used in applying for, and evaluating, exemption requests is needed. Accordingly, on March 31, 1978, the Bureau of Radiological Health distributed a draft of the criteria and related information to microwave oven manufacturers, the Associ-

ation of Home Appliance Manufacturers (AHAM), and Consumers Union and invited their review and comments. Six manufacturers, AHAM, and Consumers Union responded to the invitation to comment. The Bureau has carefully considered these comments and prepared a summary and analysis of them. The draft criteria, comments, analysis of comments, and related documents have been filed with the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. On the basis of the analysis of comments, and other relevant information, the criteria and testing guidelines have been compiled in a document entitled "Guidelines for Exemption From the Microwave Oven Labeling Requirements of 21 CFR 1030.10(c)(6)(i)," which is available upon request from the Bureau of Radiological Health (HFX-430), 5600 Fishers Lane, Rockville, MD 20857. This document also contains a summary of the rationale for the criteria and testing information.

Although the guideline has been issued in final form, it may be revised on the basis of scientific and technical information not previously considered. The Commissioner advises that an exemption will not be granted and any previously granted exemption will be rescinded after June 20, 1979, unless the manufacturer has demonstrated to the satisfaction of the Director of the Bureau of Radiological Health that the microwave ovens for which the exemption is requested, or was previously granted, conform to these guidelines or their equivalent. Comments, suggested changes, and supporting information may be submitted to the Hearing Clerk (address above), at any time (preferably in four copies identified with the Hearing Clerk docket number). Comments received by March 22, 1979, will be considered in the preparation of revised guidelines. Received comments will be incorporated into the public file on the guideline and may be seen in the office of the Hearing Clerk, between 9 a.m. and 4 p.m., Monday through Friday, except holidays.

Dated: December 15, 1978.

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

[FR Doc. 78-35425 Filed 12-21-78; 8:45 am]

[4110-03-M]

HEPATITIS B VIRUS VACCINE WORKSHOP

Public Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document announces that a public meeting will be held to give interested persons an opportunity to share, in an open workshop, experimental and developmental experiences related to Hepatitis B Virus Vaccines.

MEETING DATES: January 18 and 19, 1979.

ADDRESS: The meeting will be held in Rm. 10, Bldg. 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20014.

FOR FURTHER INFORMATION CONTACT:

Robert J. Gerety, Bureau of Biologics (HFB-230), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20014, 301-496-4288.

SUPPLEMENTARY INFORMATION: The purpose of the workshop is to share experimental and developmental experiences related to Hepatitis B Virus Vaccines, including such areas as (1) source materials, (2) methods of purification and inactivation, (3) physical-chemical characteristics, (4) in vitro testing, and (5) in vivo testing. Data gathered during recent studies by participating laboratories to evaluate a provisional Hepatitis B Vaccine Reference (Lot No. 1) will be summarized by Bureau of Biologics personnel. Members of the Safety and Efficacy Review Panel for Viral and Rickettsial Vaccine will attend the meeting.

The workshop will be held from 9 a.m. to 5 p.m., January 18 and 19, 1979, in Conferente Rm. 10, Bldg. 31C, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20014. Interested persons planning to attend should contact Robert J. Gerety, Bureau of Biologics (address above), in writing by January 18, 1979.

Dated: December 18, 1978.

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

[FR Doc. 78-35567 Filed 12-21-78; 8:45 am]

[4110-03-M]

[Docket No. 78G-0399]

PILLSBURY CO.

Filing of a Petition for Affirmation of GRAS
Status

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Pillsbury Company has filed a petition proposing that 0.02 percent karaya gum (sterculia gum) in baked goods and baking mixes be af-

firmed as generally recognized as safe (GRAS).

DATES: Comments by February 20, 1979.

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

FOR FURTHER INFORMATION CONTACT:

Corbin I. Miles, Bureau of Foods (HFF-335), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-4750.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 701(a), 52 Stat. 1055, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348, 371(a))) and the regulations for affirmation of GRAS status in § 170.35 (21 CFR 170.35), notice is given that a petition (GRASP-8G0092) has been filed by The Pillsbury Company, 311 Second Street SW., Minneapolis, MN 55414, and placed on display at the office of the Hearing Clerk, Food and Drug Administration (FDA). The petition proposes to amend § 184.1349 (21 CFR 184.1349) by affirming that an increase in the use level of karaya gum (sterculia gum) in baked goods and baking mixes from 0.002 percent to 0.02 percent is GRAS.

Any petition which meets the format requirements outlined in § 170.35 is filed by the Food and Drug Administration. There is no prefilling review of the adequacy of data to support a GRAS conclusion. Thus the filing of a petition for GRAS affirmation should not be interpreted as a preliminary indication of suitability for affirmation.

Interested persons may, on or before February 20, 1979, review the petition and/or file comments with the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. Four copies of all comments shall be submitted, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Comments should include any available information that would be helpful in determining whether the substance is, or is not, generally recognized as safe. A copy of the petition and received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 13, 1978. •

SANFORD A. MILLER,
Director, Bureau of Foods.

[FR Doc. 78-35426 Filed 12-21-78; 8:45 am]

[1505-01-M]

WHITMOYER LABORATORIES

Whitmoyer Pink Eye Powder; Withdrawal of
Approval of New Animal Drug Application

Correction

In FR Doc. 78-28060 appearing on page 46377 in the issue for Friday, October 6, 1978, in the middle column, last paragraph, in line three, the reference to "(21 U.S.C. 360 (e))" should have read "(21 U.S.C. 360b (e))".

[4110-83-M]

Health Resources Administration

ADVISORY COUNCIL AND SUBCOMMITTEE

Meetings

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following National Advisory bodies scheduled to meet during the month of January 1979:

Name: NATIONAL GUIDELINES, GOALS, PRIORITIES, AND STANDARDS SUBCOMMITTEE OF THE NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

Date and Time: January 11, 1979, 10:00 a.m.

Place: Room 703A, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201.

Open for entire meeting.

Purpose. The objectives of the National Guidelines, Goals, Priorities, and Standards Subcommittee are to study the experience nationwide in the public and private sectors with the adoption and/or adjustment of the National Guidelines for Health Planning and their impact and recommend changes as appropriate; study the experience of the Health Systems Agencies and State Health Planning and Development Agencies nationwide in implementation of high priority goals and sub-goals and their impact; advise the Council in identifying additional high priority goals and sub-goals; investigate and coordinate information on demonstrations underway by provider, reimbursement, regulatory, labor, industry, and community groups on sub-goals, such as those on alcoholism and prevention; study, investigate and identify research needs appropriate to the formulation, adjustment and refinement of the National Guidelines, and study and develop improved indicators to assess the impact of the Guidelines or the need for revisions; and recommend to the Council on the

need for further development and/or revision of the National Guidelines.

Name: IMPLEMENTATION AND ADMINISTRATION SUBCOMMITTEE OF THE NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

Date and Time: January 11, 1979, 6:00 p.m. (Tentative).

Place: Hyatt Regency, Room Columbia C, 400 New Jersey Avenue, NW., Washington, D.C. 20001

Open for entire meeting.

Purpose. The objective of the Implementation and Administration Subcommittee is to study and make recommendations on the implementation and administration of Titles XV and XVI of the Public Health Service Act. Specific areas for the Subcommittee's consideration are (1) the impact of HEW's implementation/administration on the effectiveness of Health Systems Agencies and State Health Planning and Development Agencies; (2) the effectiveness of the interrelationships between health planning agencies and HEW, Central and Regional Offices; (3) the timing and strategy of implementation and of the dissemination and distribution of regulatory and technical material; (4) how to better meet the needs of HSAs and SHPDAs; and (5) the review of the Council's responsibilities under section 1122 of the Social Security Act.

Name: TECHNOLOGY AND PRODUCTIVITY SUBCOMMITTEE OF THE NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

Date and Time: January 11, 1979, 7:00 p.m.

Place: Hyatt Regency, Room Columbia C, 400 New Jersey Avenue, NW., Washington, D.C. 20001

Open for entire meeting.

Purpose. The objective of the Technology and Productivity Subcommittee is to advise the full Council on matters related to the productivity of the health care delivery system and to the implications of new medical technology for the organization, delivery and equitable distribution of health care services. "Technology" includes the drugs, devices and medical and surgical procedures used in medical care and the organizational and supportive systems within which such care is delivered. "Productivity" is the efficiency with which health care is delivered.

The Subcommittee is to deliberate and to make recommendations to the full Council on matters chosen from among those brought to it by Council members, HEW staff and advisory committees, other Federal departments, congressional committees and staff, provider groups and the public at large. The subcommittee in addition

will study and investigate the current needs for assistance of HSAs and SHPDAs in the area of evaluating productivity improvement and new medical technology, help transmit concerns of HSAs and SHPDAs to appropriate Federal agencies, and review the current resources both within the Federal Government and among the educational, research and other developmental agencies for providing needed assistance to HSAs and SHPDAs. In addition, it will review technology assessment activities within the Department in order to assure they are relevant to the needs of the HSAs and are useful in the development and implementation of national standards, goals, and guidelines, and for the establishment of priorities with those goals.

Agenda for Subcommittees: Consideration of issues related to the national guidelines, goals, standards, implementation and administration of Titles XV and XVI and the Council's responsibilities in the area of new medical technology and productivity.

Name: NATIONAL COUNCIL ON HEALTH PLANNING AND DEVELOPMENT

Date and Time: January 12, 1979, 8:45 a.m.

Place: Main Auditorium, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

Open for entire meeting.

Purpose. The National Council on Health Planning and Development is responsible for advising and making recommendations with respect to (1) the development of national guidelines under section 1501 of Pub. L. 93-641, (2) the implementation and administration of Title XV and XVI of Public Law 93-641, and (3) an evaluation of the implications of new medical technology for the organization, delivery and equitable distribution of health care services. In addition, the Council advises and assists the Secretary in the preparation of general regulations to carry out the purposes of section 1122 of the Social Security Act and on policy matters arising out of the implementation of it, including the coordination of activities under that section with those under other parts of the Social Security Act or under other Federal or federally assisted health programs. The Council considers and advises the Secretary on proposals submitted by the Secretary under the provisions of section 1122(d)(2) that health care facilities or health maintenance organizations be reimbursed for expenses related to capital expenditures notwithstanding that under sec-

tion 1122(d)(1) there would otherwise be exclusion of reimbursement for such expenses.

Agenda: (1) Continuation of discussions of subcommittee plans and operations; and (2) status reports from the Administrator, Health Resources Administration; Director, Bureau of Health Planning; and Director, Bureau of Health facilities, Financing and Conversion.

Anyone requiring information regarding the subject Council should contact Mrs. S. Judy Silsbee, Executive Secretary, National Council on Health Planning and Development, Room 10-27, Center Building, 3700 East-West Highway, Hyattsville, Maryland, 20782. Telephone (301) 436-7175.

Agenda items are subject to change as priorities dictate.

Dated: December 12, 1978.

JAMES A. WALSH,
Associate Administrator for
Operations and Management.

[FR Doc. 78-35571 Filed 12-21-78; 8:45 am]

[4110-08-M]

National Institutes of Health

REPORT ON BIOASSAY OF N-(1-NAPHTHYL)ETHYLENEDIAMINE DIHYDROCHLORIDE FOR POSSIBLE CARCINOGENICITY

Availability

N-(1-Naphthyl)ethylenediamine dihydrochloride (CAS 1465-25-4) 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: A bioassay for the possible carcinogenicity of N-(1-naphthyl)ethylenediamine dihydrochloride was conducted using Fischer 344 rats and B6C3F1 mice. Applications of the chemical include use as a diagnostic reagent to determine levels of sulfanilamide and other compounds in blood and other body fluids. N-(1-naphthyl)ethylenediamine dihydrochloride was administered in the feed, at either of two concentrations, to groups of 50 male and 50 female animals of each species.

Under the conditions of this bioassay, dietary administration of N-(1-naphthyl)ethylenediamine dihydrochloride was not carcinogenic in Fisher 344 rats or B6C3F1 mice.

Single copies of the report are available from the Office of Cancer Communications, National Cancer Institute, Building 31, Room 10A21, Na-

tional Institutes of Health, Bethesda, Maryland 20014.

(Catalogue of Federal Domestic Assistance Program Number 13.393, Cancer Cause and Prevention Research)

Dated: December 14, 1978.

DONALD S. FREDRICKSON,
Director, National
Institutes of Health.

[FR Doc. 78-35299 Filed 12-21-78; 8:45 am]

[4110-92-M]

Office of Human Development Services

FEDERAL ALLOTMENT TO STATES FOR SOCIAL SERVICES EXPENDITURES PURSUANT TO TITLE XX OF THE SOCIAL SECURITY ACT

Promulgation for Fiscal Year 1980—Revised

In FR Doc. 78-32060 published in the FEDERAL REGISTER at page 53060 on November 15, 1978, the limitations promulgated to the States were incorrectly prepared. Accordingly, the promulgation contained in such document is rescinded and the promulgation, as corrected, is set forth below in its entirety.

Promulgation is made of the Federal allotment for Fiscal Year 1980 for purposes of grants to States under Title XX of the Social Security Act pursuant to section 2002(a)(2) of the Act which provides that the Federal allotment shall be determined and promulgated in accordance with said section.

For Fiscal Year 1980, the allotment limits are based on the Bureau of Census population statistics contained in its publication, "Current Population Reports" (Series P-25, No. 727, July 1978) which is the most recent satisfactory data, available from the Department of Commerce at this time as to the population of each State and of all States.

It is hereby promulgated, for purposes of grants to States for social services under title XX, that the Federal allotment to each of the 50 States and the District of Columbia for the fiscal year ending September 30, 1980, as determined pursuant to the Act and on the basis of said population data, shall be as set forth below:

State	Federal Allotment
Total.....	\$2,500,000,000
Alabama.....	42,642,000
Alaska.....	4,703,000
Arizona.....	26,533,000
Arkansas.....	24,776,000
California.....	253,037,000
Colorado.....	30,266,000
Connecticut.....	35,917,000
Delaware.....	6,725,000
District of Columbia.....	7,974,000
Florida.....	97,674,000
Georgia.....	58,336,000
Hawaii.....	10,343,000
Idaho.....	9,903,000
Illinois.....	129,951,000
Indiana.....	61,595,000
Iowa.....	33,270,000
Kansas.....	26,880,000
Kentucky.....	39,962,000
Louisiana.....	45,312,000

Maine.....	12,538,000
Maryland.....	47,831,000
Massachusetts.....	66,818,000
Michigan.....	105,497,000
Minnesota.....	45,936,000
Mississippi.....	27,608,000
Missouri.....	55,482,000
Montana.....	8,794,000
Nebraska.....	18,039,000
Nevada.....	7,315,999,000
New Hampshire.....	9,811,000
New Jersey.....	84,696,000
New Mexico.....	13,752,000
New York.....	207,135,000
North Carolina.....	63,848,000
North Dakota.....	7,546,000
Ohio.....	123,664,000
Oklahoma.....	32,485,000
Oregon.....	27,458,000
Pennsylvania.....	136,191,000
Rhode Island.....	10,805,000
South Carolina.....	33,236,000
South Dakota.....	7,962,000
Tennessee.....	49,680,000
Texas.....	148,267,000
Utah.....	14,653,000
Vermont.....	5,581,000
Virginia.....	59,341,000
Washington.....	42,273,000
West Virginia.....	21,483,000
Wisconsin.....	53,784,000
Wyoming.....	4,692,000

Dated: December 7, 1978.

ERNEST L. OSBORNE,
Commissioner, Administration
for Public Services.

Dated: December 15, 1978.

Approved by: Arabella Martinz,
Assistant Secretary for
Human Development Services.

[4510-23-M]

INTERAGENCY TASK FORCE ON WORKPLACE SAFETY AND HEALTH MAKING PREVENTION PAY

Proposed Final Recommendations; Request for
Public Comment

AGENCY: Interagency Task Force on Workplace Safety and Health.

ACTION: Request for Public Comment.

SUMMARY: This publication reviews the purposes for which the Interagency Task Force on Workplace Safety and Health was created. It requests comments from the public on the staff's proposed final recommendations contained in its Draft Final Report titled *MAKING PREVENTION PAY*, to the Task Force heads.

DATES: Comments should be received by February 20, 1979.

ADDRESS: Mail comments to: Interagency Task Force on Workplace Safety and Health, 1815 North Lynn Street, Rosslyn, Va. 22209.

FOR FURTHER INFORMATION
CONTACT:

Richard I. Bergman, Executive Director, Interagency Task Force on Workplace Safety and Health, 1815 North Lynn Street, Rosslyn, Va. 22209.

SUPPLEMENTARY INFORMATION:
By memorandum dated August 5, 1977, President Carter created the Interagency Task Force on Workplace Safety and Health, jointly chaired by Secretary of Labor Marshall and Office of Management and Budget Director McIntyre, to consider ways of improving the Federal Government effort to protect the safety and health of American workers. Specifically, the President directed that the Task Force focus on the following:

Explore incentives that might supplement direct workplace safety regulations.

Evaluate government-wide administration of Federal Workplace safety and health activities, including duplication, overlaps and gaps in Federal agency jurisdiction.

Review other ways to improve the safety and health efforts of all Federal agencies, including those programs that affect Federal employees and the resources devoted to them.

In formulating its recommendations, the Task Force strongly encouraged information and views from the public at large, including employers, workers, and other interested parties. The Task Force released its **FIRST RECOMMENDATIONS** Report to the public in September 1978 (GPO #9-10086).

The Task Force has now completed additional and different proposed recommendations which are contained in a draft final report to the Task Force co-chairmen titled *Making Prevention Pay*. This notice is published in the FEDERAL REGISTER to solicit public comment on these staff proposed recommendations. Simultaneously, the proposed recommendations will be reviewed by potentially affected government agencies. The Task Force co-chairmen will then consider comments from both the public and government agencies when making Task Force recommendations final.

The Draft Executive Summary of Recommendations from the Draft Final Report *Making Prevention Pay* reads as follows:

The recommendations contained in this Final Report are designed to reduce serious workplace injuries and to do so in a manner which is more cost-effective than the present Federal approach. They compliment, and in some cases reinforce, ideas for regulatory improvement now being discussed within the Occupational Safety and Health Administration (OSHA) and other Federal agencies.

RECOMMENDATIONS FOR MORE EFFECTIVE WORKPLACE SAFETY AND HEALTH ENFORCEMENT (CHAPTER III)

Important changes have occurred in occupational safety and health since OSHA's 1971 start-up as the most visi-

ble Federal regulatory agency in this field.

Workers are more informed and concerned about job safety and health issues. Safety engineers and managers, once relegated to obscure roles in many plants and industries, now play more prominent parts. General public support for government regulation of workplace safety and health is high, though there are sharp differences of opinion over means, ends and costs.

OSHA itself, as the President noted in his Memorandum chartering this Task Force, has begun internal reforms to identify the most serious hazards workers face. More recently it has received public recognition for deleting unnecessary standards.

But OSHA has also labored under handicaps. It seems inadequately funded to meet the expectations raised by its broad legislative mission of assuring all workers "so far as possible" a safe and healthy workplace. Few professional and technical staff were hired during its formative years. The demands of developing standards and conducting as many inspections as possible to meet the Congress' mandate left the agency few resources to evaluate the effectiveness of its programs or move in new directions. As a result, OSHA knows little more about what works to prevent injuries today than it did in 1971. While factors out of OSHA's control contributed, the national rate of serious (lost workday) injuries has not declined since that time.

The recommendations which follow are designed to provide better focused and more cost-effective enforcement by prioritizing enforcement resources on establishments with high rates of lost workday injuries; concentrating on reduced injuries rather than citations and compliance with procedures; recognizing employers with low total injury rates; and affording standards violators more flexibility in hazard control while removing any financial incentives for delayed abatement.

The Task Force recommends that OSHA:

- develop and test an enforcement strategy which sends inspectors first to High Injury Rate Establishments (HIRE), and then to establishments most likely to have detectable serious standards violations;

- make more effective use of inspectors by testing a requirement that area directors first respond to employee complaints with a letter to the employer rather than an on-site inspection, except in cases of imminent danger or serious mobile site hazards;

- begin systematically to identify hazards for which engineering controls can be implemented on normal equipment replacement cycles instead of by retrofitting;

- develop a penalty system that will assess noncomplying firms a penalty which precisely equals the economic benefits of their non-compliance;

- maintain lists of substitutes for hazardous substances regulated by its standards; and

- develop ergonomic standards where existing research makes swift development of such standards feasible.

RECOMMENDATIONS TO SUPPLEMENT DIRECT REGULATION BY MAKING PRIVATE SECTOR PREVENTION PAY (CHAPTER IV)

Conventional wisdom says that safety pays. The Task Force found it often does not, at least in monetary terms. In many industries the average cost of worker injuries is sufficiently small that management focuses on other cost problems first. In industries where the cost of injuries is high (from 6 to 33 times the overall national average), it may also be high for many other firms, making it difficult for one employer to spend more for prevention. The recommendations which follow are designed to make prevention pay by increasing the effective cost of injuries to high-rate firms and rewarding their low-rate competitors. They also increase direct financial assistance to high rate firms in hazardous industries to help them take preventive actions and avoid these higher injury costs.

The Task Force recommends that:

- the Federal Tax Code be modified to prevent high-rate employers from deducting that part of their workers' compensation cost which exceeds the average cost for their industry and size class, and allow low-rate employers to deduct the full average cost even if their own cost is much lower; and

- when general economic conditions permit, a limited increase in direct Federal assistance be provided to high-rate firms in hazardous industries in a way which preferentially helps smaller and less profitable firms increase both their capital and non-capital expenditures for prevention.

RECOMMENDATIONS TO SUPPLEMENT DIRECT REGULATION BY COOPERATIVE PROGRAMS WITH THE PRIVATE SECTOR (CHAPTER V)

The Task Force found that workplace injuries have multiple causes which involve behavioral and organizational as well as physical equipment components. We also found that safety performance is inextricable from what a firm makes, how it makes it, and how well it is managed. Since many of these accident-related factors are difficult for direct regulation to impact, we concluded that injury prevention must be the shared responsibility of management, workers and

unions, as well as the Federal Government. The recommendations which follow are designed to sponsor cooperative prevention programs among all these groups by providing better information on engineering controls for identified hazards, encouraging joint labor/management efforts at both the industry and plant levels, and placing greater reliance on the ability of employers who have performed well in the past to monitor their own performance.

The Task Force recommends that:

- OSHA, NIOSH and other interested Federal agencies fund a cooperative program to abstract, store and disseminate on a fee basis information on available control technology for workplace hazards. Private sector users and other interested groups should be represented on a board of directors or advisors to the program;

- significant knowledge gaps be identified, and gap-filling research be funded jointly with the private sector;

- the program be evaluated for continuation after three years, and if it is continued, established as a separate quasi-governmental organization;

- OSHA and NIOSH should stimulate the formation of joint worker/management safety committees at the industry level in industries where their chance of success is high;

- OSHA and NIOSH should encourage formation of plant level worker/management safety committees where factors for their successful operation appear to exist; and

- OSHA and NIOSH should evaluate employer/employee self-certification programs for health hazard abatement, and sponsor demonstration projects.

RECOMMENDATION TO REDUCE REGULATORY DUPLICATION AND WASTE (CHAPTER VI)

Recent polls show the public continues to support Federal regulation of job safety and health, but wants to be sure it is getting its full money's worth. Waste can be avoided by reducing overlaps and gaps in interagency enforcement, standard-setting and research efforts. Waste can also be avoided by improving agencies' internal safety and health programs and reducing the taxpayers' bill for compensating Federal workers' injuries and illnesses, now costing the Treasury over \$1 billion per year.

To reduce waste by reducing interagency overlaps and gaps, the Task Force recommends that:

- OSHA focus its resources on industries where other agencies have no regulatory authority, and enter into agreements with agencies that have such authority to assume more responsibility based on mutually agreeable

standards and feasible enforcement procedures;

- an Executive Order spell out standard administrative procedures for resolving interagency jurisdictional disputes which include incentives for agencies to seek rather than avoid resolution;

- part of the budget of key DHEW agencies doing research related to occupational safety and health (NIOSH, NCI, NIEHS) be allocated to be spent solely at the request of OSHA to meet its specific research needs. One appropriate mechanism might be the issuance of individual purchase vouchers by OSHA specifying the work to be done and its cost;

- standing interagency committees to identify and prioritize applied and basic research needs be established, with membership drawn from the research, regulatory and administrative arms of agencies doing and using the research;

- national morbidity and mortality statistics correlated with industry of employment be developed and periodically reported, with the Social Security Administration and the National Center for Health Statistics acting as lead agencies;

- DHEW and social regulatory agencies jointly develop generally accepted procedures for projecting the public health impacts of proposed environmental, workplace safety and health, and other social regulations. This might include research and demonstration projects, as well as new analytical techniques; and

- OMB experiment with cross-cutting budget analyses of hazard identification, prevention, and medical care/compensation programs in the social regulatory and health care departments and agencies.

To improve safety and health for Federal employees, the Task Force recommends that:

- the Federal Employees Compensation Act be amended to charge the present value of the full compensation award to the operating establishment the year such awards are made, and an appropriate appeal procedure be established to allow agencies to challenge initial awards made to Federal employees claiming injury or illness on their jobs;

- Federal agencies and OSHA begin immediate development of agency-level causal data systems to identify high-risk areas and establishments within participating agencies, and injury prevention resources be focused on those identified high-risk areas to secure maximum gains in Federal working conditions; and

- an Executive Order require representatives of OSHA and GSA to negotiate a consistent, structured basis for resolving leased space safety conflicts, subject to monitoring by OMB and as-

sistance by the Federal Mediation and Conciliation Service at OMB's request.

RECOMMENDATIONS TO RECONCILE REGULATORY IMPACTS AND BUILD A BROAD-ER CONSTITUENCY FOR OSHA (CHAPTERS VII AND VIII)

The Task Force found that compliance with OSHA regulations was often hindered at individual plants by simultaneous requirements of other Federal regulatory agencies; that the OSHA inspector was often viewed by employers as a hinderer more concerned with citations than reducing injuries; and that OSHA itself is often caught between the polarized views of labor and management, which hinder the agency in developing its own concept of the public interest.

To help reconcile cumulative regulatory impacts, help OSHA be perceived as a firm but fair helper, and begin to build it a broader and less polarized constituency, the Task Force recommends that:

- an Establishment Stewardship demonstration program be developed in which OSHA inspectors become establishment stewards and are assigned responsibility for between 100 to 200 workplace establishments; charged with working with management and labor to reduce serious injury rates by at least 5-10% a year; and authorized to assist establishments to obtain available Federal assistance and coordinate compliance with other Federal agencies when appropriate;

- all or part of any Federal assistance towards the cost of compliance with its regulations be appropriated so far as feasible to OSHA's budget for regular budget review, with subsequent distribution to individual firms;

- the government develop and evaluate the feasibility of a regulatory cap limiting the absolute level and the rate of increase of yearly expenditures which must be made by individual firms for compliance with new social regulations, with priorities established by local choices, except for imminent danger to workers or the community; and

- OSHA develop and disseminate to the general public its own view of the public interest, including: the serious nature and extent of the injuries and illnesses it intends to prevent; their short- and long-range impacts on and off the job; and a set of expectations of what workers, their families, and the public should expect in workplace safety and health, for which the agency can be held accountable.

Hindsight is a great clarifier; and it seems fair to conclude that both workers and employers might be better served by administering and promoting the OSH Act as a hazardous industries and occupations program rather than an all-correcting omnibus safety and health statute. By adjusting the expectations of both its supporters

and its opponents to this more focused reality, and by concentrating its efforts in areas where concrete gains can be realized, OSHA may help lay the foundations of a broader constituency which neither demands an all-out response to every hazard, or fears irrational disruption from every regulatory act. That adjustment, we think, is a necessary step which both underlies and goes beyond the specific recommendations in this Report.

A complete copy of the Draft Final Report as prepared by the staff can be obtained by writing to the Task Force at 1815 North Lynn Street, Rosslyn, Va. 22209. If you have received the Task Force's First Recommendations Report, you will receive a copy of the Draft Final Report and do not need to request one.

Persons who are interested in assisting the Task Force finalize its recommendations by responding to this notice should do so in writing to the Interagency Task Force on Workplace Safety and Health, 1815 North Lynn Street, Rosslyn, Va. 22209, by February 20, 1979.

When responding, please first copy the recommendation(s) on which you are commenting, followed by your comments, kept as brief and specific as possible.

Signed at Washington, D.C., this 18th day of December, 1978.

RICHARD I. BERGMAN,
Executive Director.

[FR Doc. 78-35631 Filed 12-21-78; 8:45 am]

[4310-84-M]

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[INT DES 78-50]

FEDERAL COAL MANAGEMENT PROGRAM

Public Hearings and Public Meetings

By FEDERAL REGISTER Notice dated December 15, 1978 (FR 43, No. 242, p. 58778) the Availability of the Draft Environmental Statement on the Federal Coal Management Program was announced and copies of the document were made available for public review and comment. In the Notice information was provided that public hearings and public meetings would be conducted during late January and early February 1979 throughout the United States.

The purpose of this Notice is to specify the dates and location for the subject hearings and meetings. Hearings and meetings will be held at the following locations (see attached list). All other procedures regarding the hearings as contained in the December 15, 1978 Notice remain unchanged.

ARNOLD E. PETTY,
Acting Associate Director,
Bureau of Land Management.

Date	City and State	Location
PUBLIC MEETINGS		
January 3, 1979	Albuquerque, New Mexico	Tesuque Room, Albuquerque Convention Center, Second Street
January 3, 1979	Denver, Colorado	Wyer Auditorium Denver Public Library, 1357 Broadway
January 4, 1979	Salt Lake City, Utah	Salt Palace Little Theater, 100 South West Temple
January 4, 1979	Cheyenne, Wyoming	Little America Motel, West of Cheyenne
January 5, 1979	Grand Junction, Colorado	City Auditorium, Fifth and Rood Street
January 5, 1979	Sheridan, Wyoming	Sheridan Center Motor Inn, 609 North Main
January 8, 1979	Price, Utah	Gomer Peacock Auditorium, College of Eastern Utah
January 8, 1979	Billings, Montana	Petro West Room, Student Union Building, Eastern Montana College
January 9, 1979	Craig, Colorado	New City Hall Building, 300 West 4th Street
January 9, 1979	Miles City, Montana	Rooms 106 and 107, Miles Community College
January 10, 1979	Rock Springs, Wyoming	Holiday Inn, 1675 Deware Drive
January 10, 1979	Bismarck, North Dakota	Highway Department Auditorium, N. D. Highway Department Building, State Capitol Complex
PUBLIC HEARINGS		
January 22, 1979	Salt Lake City, Utah	Salt Palace Little Theater, 100 South West Temple
January 22, 1979	Albuquerque, New Mexico	Cochiti Room, Albuquerque Convention Center, Second Street
January 23, 1979	Casper, Wyoming	Ramada Inn, 123 West E Street
January 23, 1979	Craig, Colorado	New City Hall Building, 300 West 4th Street
January 24, 1979	Denver, Colorado	Wyer Auditorium, Denver Public Library, 1357 Broadway
January 24, 1979	Billings, Montana	Petro West Room, Student Union Building, Eastern Montana College
January 25, 1979	Bismarck, North Dakota	Highway Department Auditorium, N. D. Highway Department Building, State Capitol Complex
January 30, 1979	Chicago, Illinois	Buckingham Room, Continental Plaza Hotel, 909 North Michigan Avenue
February 1, 1979	Lexington, Kentucky	Keeneland Hall, Hilton Hotel, 1938 Stanton Way
February 6, 1979	Washington, D.C.	Main Auditorium, Main Interior Building, 18th and C Streets, N.W.

[FR Doc. 78-35740 Filed 12-21-78; 8:45 am]

[4310-84-M]

[M 42496]

MONTANA

Order Providing for Opening of Public Land

DECEMBER 13, 1978.

In an exchange of lands under the provisions of Section 206 of the Act of October 21, 1976, 90 Stat. 2756, 43 U.S.C. 1716, the following land has been reconveyed to the United States:

PRINCIPAL MERIDIAN, MONTANA

T. 8 S., R. 60 E.,
Sec. 15, SW $\frac{1}{4}$ SW $\frac{1}{4}$ and S $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$;
AND
Sec. 22, W $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$, NE $\frac{1}{4}$ NW $\frac{1}{4}$, AND
W $\frac{1}{2}$ NW $\frac{1}{4}$.

The area described contains 200 acres in Carter County, Montana.

The land is located in southeastern Montana near the community of

Alzada and approximately 50 miles southeast of the city of Broadus. Elevation of the area is 3,500 feet above sea level, and the topography is characterized by the Little Missouri River and its floodplain; narrow deeply incised tributaries; and a flat to moderately undulating monoclinical surface which dips at a consistent low angle toward the Little Missouri River. Vegetation consists primarily of big sagebrush, silver sagebrush, green needlegrass, western wheatgrass, blue grama, American vetch, greasewood, prickly pear, green ash, box elder, chokecherry, and snowberry. In the past the land has been used for livestock grazing, wildlife habitat, and hunting activities. The land provides approximately 45 acres of riparian habitat and public access to the Little Missouri River. The land will be managed, together with adjoining public lands, for multiple use.

Subject to valid existing rights, the land described in paragraph one hereof will be open to operation of the public land laws at 10 a.m., January 27, 1979. The government previously owned the minerals in the W $\frac{1}{2}$ NW $\frac{1}{4}$, Section 22, and this land will remain open to the mining and mineral leasing laws. No minerals were acquired in the balance of the land. The lands listed in paragraph one are within the ranch holdings of the exchange proponent and a grazing license will be issued upon completion of a range survey to establish carrying capacities and the filing of a valid grazing license application.

Inquiries concerning the land should be addressed to the Chief, Branch of Lands and Minerals Operations, Bureau of Land Management, P.O. Box 30157, Billings, Montana 59107.

EDGAR D. STARK,
Acting Chief, Branch of Lands
and Minerals Operations.

[FR Doc. 78-35539 Filed 12-21-78; 8:45 am]

[4310-84-M]

[Wyoming 65973]

WYOMING

Application

DECEMBER 15, 1978.

Notice is hereby given that pursuant to Section 28 of the Mineral Leasing Act of 1920, as amended (30 U.S.C. 185), the Montana-Dakota Utilities Co. of Bismarck, North Dakota filed an application for a right-of-way to construct an 8 inch pipeline for the purpose of transporting natural gas across the following described public lands:

SIXTH PRINCIPAL MERIDIAN, WYOMING

T. 49 N., R. 93 W.,
Sec. 5, lot 1, S $\frac{1}{2}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$
and SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 6, S $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 7, lots 1 and 2, NW $\frac{1}{4}$ NE $\frac{1}{4}$ and
NE $\frac{1}{4}$ NW $\frac{1}{4}$.
T. 50 N., R. 93 W.,
Sec. 32, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 33, SW $\frac{1}{4}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$
and SW $\frac{1}{4}$ SW $\frac{1}{4}$.
T. 49 N., R. 94 W.,
Sec. 11, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 12, S $\frac{1}{2}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$ and
NW $\frac{1}{4}$ SE $\frac{1}{4}$.

The pipeline will transport natural gas produced from the Federal #1-11 Well located in the SE $\frac{1}{4}$ SE $\frac{1}{4}$ of sec. 11, T. 49 N., R. 94 W., to a point of connection with Montana-Dakota Utilities Co.'s existing pipeline in the

SW¼NE¼ of sec. 33, T. 50 N., R. 93 W., 6th P.M., Big Horn County, Wyoming.

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, 1700 Robertson Avenue, P.O. Box 119, Worland, Wyoming 82401.

WILLIAM S. GILMER,
Acting Chief, Branch of
Lands and Minerals Operations.

[FR Doc. 78-35540 Filed 12-21-78; 8:45 am]

[4310-70-M]

National Park Service

CAPE COD NATIONAL SEASHORE ADVISORY COMMISSION

Meeting

Notice is hereby given in accordance with Pub. L. 92-463 that a meeting of the Cape Cod National Seashore Advisory Commission will be held on Friday, January 19, 1979, at 1:30 pm at the Headquarters Building, Cape Cod National Seashore, Marconi Station Area, South Wellfleet, Massachusetts.

The Commission was established pursuant to Pub. L. 91-383 to meet and consult with the Secretary of the Interior on general policies and specific matters relating to the development of Cape Cod National Seashore.

The Commission will consider the following matters: (1) Status of Beachcomber property; (2) Follow-up report on recommendations of Ponds Management Subcommittee; (3) Update on planning effort to replace Coast Guard beach facilities; and (4) Report on restoration of Pamet Valley Cranberry Bog.

The meeting is open to the public. It is expected that 15 persons will be able to attend the session in addition to Commission members.

Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the official listed below at least seven days prior to the meeting.

Further information concerning this meeting may be obtained from Lawrence C. Hadley, Superintendent, Cape Cod National Seashore, South Wellfleet, Massachusetts 02663, Telephone 617-349-3785. Minutes of the meeting will be available for public information and copying four weeks after the

meeting at the office of the Superintendent, Cape Cod National Seashore, South Wellfleet, Massachusetts.

LAWRENCE C. HADLEY,
Superintendent,
Cape Cod National Seashore.

DECEMBER 11, 1978.

[FR Doc. 78-35587 Filed 12-21-78; 8:45 am]

[4310-70-M]

GOLDEN GATE NATIONAL RECREATION AREA ADVISORY COMMISSION

Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Golden Gate National Recreation Area Advisory Commission will be held at 7:30 p.m. (PST) on January 10, 1979 at Fort Mason Visitor Center, GGNRA Headquarters, Fort Mason, San Francisco, CA.

The Advisory Commission was established by Pub. L. 92-589 to provide for the free exchange of ideas between the National Park Service and the public and to facilitate the solicitation of advice or other counsel from members of the public on problems pertinent to the National Park system in Marin and San Francisco counties.

Members of the Commission are as follows:

Mr. Frank Boerger, Chairman
Ms. Amy Meyer, Secretary
Mr. Ernest Ayala
Mr. Richard Bartke
Mr. Fred Blumberg
Ms. Daphne Greene
Mr. Peter Haas, Sr.
Mr. John Jacobs
Ms. Gimmy Park Li
Mr. Joseph Mendoza
Mr. John Mitchell
Mr. Merritt Robinson
Mr. Jack Spring
Dr. Edgar Wayburn
Mr. Joseph Williams

The major agenda items will be election of 1979 officers, a vote on the San Francisco pet policy guidelines, a vote on the draft prospectus for the Marin Headlands artist-in-residence prospectus, a trails committee update, and an update on the draft General Management Plan timeframe for 1979.

This meeting is open to the public. Any member of the public may file with the Commission a written statement concerning the matters to be discussed.

Persons wishing to receive further information on this meeting or who wish to submit written statements may contact Lynn H. Thompson, General Superintendent, Golden Gate National Recreation Area, Fort Mason,

San Francisco, CA 94123, telephone 415-556-2920.

Minutes of the meeting will be available for public inspection by February 10, 1979 in the Office of the General Superintendent, Golden Gate National Recreation Area, Fort Mason, San Francisco, CA.

Dated: December 15, 1978.

LYNN H. THOMPSON,
General Superintendent, Golden
Gate National Recreation
Area.

[FR Doc. 78-35588 Filed 12-21-78; 8:45 am]

[4310-55-M]

Fish and Wildlife Service

FEDERAL AID IN FISH AND WILDLIFE RESTORATION PROGRAMS

Availability of Final Environmental Impact Statement

AGENCY: Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of Availability for Public Comment on Final Environmental Impact Statement (FEIS) on the Federal Aid in Fish and Wildlife Restoration Programs.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, Pub. L. 91-190, the Department of the Interior has prepared a Final Environmental Impact Statement (FEIS) on the Federal Aid in Fish and Wildlife Restoration programs. The FEIS considers the impacts of the two grant programs on populations of big and small game, migratory game birds, sport fish, non-game fish and wildlife, threatened and endangered species, several categories of land, air, water quality, soil and economic conditions, among other topics. The FEIS discusses six alternatives to the current program which would alter the degree of Federal funding and control of the program.

ADDRESSES: Copies of the final statement are available for inspection at the following locations:

Associate Director—Federal Assistance, U.S. Fish and Wildlife Service, 18th and C Streets, N.W.—Room 3024, Washington, D.C. 20240.

Regional Director, U.S. Fish and Wildlife Service, Lloyd 500 Building, 500 N.E. Multnomah Street, Portland, Oregon 97232.

Regional Director, U.S. Fish and Wildlife Service, 500 Gold Avenue, S.W., Albuquerque, New Mexico 87103.

Regional Director, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111.

Regional Director, U.S. Fish and Wildlife Service, 17 Executive Park Drive, Atlanta, Georgia 30347.

Regional Director, U.S. Fish and Wildlife Service, 1 Gateway Center, Suite 700 Newton Corner, Massachusetts 02158.
Regional Director, U.S. Fish and Wildlife Service, 10597 W. 6th Avenue, Lakewood, Colorado 80215.
Alaska Area Director, U.S. Fish and Wildlife Service, 1101 E. Tudor Road, Anchorage, Alaska 99507.

A limited number of single copies are available and may be obtained by writing the Chief, Division of Federal Aid, at the address below.

FOR FURTHER INFORMATION, CONTACT:

Charles K. Phenicie, Chief, Division of Federal Aid, U.S. Fish and Wildlife Service, Washington, D.C. 20240, phone (703) 235-1526.

Dated: December 22, 1978.

LARRY E. MEIEROTTO,
Deputy Assistant Secretary.

[FR Doc. 78-35405 Filed 12-21-78; 8:45 am]

[7020-02-M]

INTERNATIONAL TRADE COMMISSION

[ITA-203-5]

STAINLESS STEEL AND ALLOY TOOL STEEL

Investigation and Hearing

Investigation instituted. Following receipt of a petition on November 30, 1978, filed by the Tool and Stainless Steel Industry Committee and the United Steelworkers of America, AFL-CIO, the U.S. International Trade Commission on December 11, 1978, instituted an investigation under section 203(i)(2) and (i)(3) of the Trade Act of 1974 for the purpose of gathering information in order that it might advise the President of its judgment as to the probable economic effect on the domestic industry concerned of the termination of import relief presently in effect with respect to the stainless steel and alloy tool steel provided for in items 923.20 through 923.26, inclusive, of the Appendix to the Tariff Schedules of the United States. Import relief presently in effect with respect to such articles is scheduled to terminate at the close of June 13, 1979, unless extended by the President. The relief is provided for in Proclamation 4445 of June 11, 1976 (41 FR 24101), as modified by Proclamation 4477 of November 16, 1976 (41 FR 50960), Proclamation 4509 of June 15, 1977 (42 FR 30829), and Proclamation 4559 of April 5, 1978 (43 FR 14433).

Public hearing ordered. A public hearing in connection with this investigation will be held in Washington, D.C., at 10 a.m., e.s.t., on Tuesday, March 6, 1979, in the Hearing Room, U.S. International Trade Commission Building, 701 E Street, N.W. Requests

for appearances at the hearing should be received in writing by the Secretary to the Commission at his office in Washington no later than noon on March 1, 1979.

Suggested prehearing procedures. To facilitate the hearing process, it is requested that persons wishing to appear at the hearing submit prehearing briefs enumerating and discussing the issues which they wish to raise at the hearing. Such prehearing briefs should be submitted to the Secretary of the Commission no later than the close of business Monday, February 26, 1979. The Secretary will make copies of such briefs available to the public. While this does not prohibit submission of prepared statements in accordance with § 201.12(d) of the Commission's Rules of Practice and Procedure (19 CFR § 201.12(d)), it would be unnecessary to submit such a statement if a prehearing brief is submitted instead. Any such statements will, of course, be made a part of the transcript. Oral presentations, however, should, to the extent possible, be limited to issues raised in the prehearing briefs.

Prehearing conferences will be held on Tuesday, February 12, 1979, at 10:00 a.m. and Friday, March 2, 1979, at 10:00 a.m. in Room 117 of the U.S. International Trade Commission Building.

Persons not represented by counsel or public officials who have relevant matters to present may give testimony without regard to the suggested prehearing procedures outlined above.

Inspection of petition. The petition filed in this case is available for public inspection at the Office of the Secretary, U.S. International Trade Commission, and at the New York City office of the U.S. International Trade Commission located at 6 World Trade Center.

Issued: December 19, 1978.

By order of the Commission.

KENNETH R. MASON,
Secretary.

[FR Doc. 78-35689 Filed 12-21-78; 8:45 am]

[4410-01-M]

DEPARTMENT OF JUSTICE

UNITED STATES CIRCUIT JUDGE NOMINATING COMMISSION; EIGHTH CIRCUIT PANEL

Meeting

The Eighth Circuit Panel of the United States Circuit Judge Nominating Commission will meet in St. Louis, Missouri on January 8, 1979, at the Breckenridge Pavillion Hotel, in the Board Room at 8:30 a.m. The morning session will be open to the public. The afternoon session will be devoted to a

discussion of candidates and will be closed to the public pursuant to Pub. L. 92-463, Section 10(D) as amended. (CF. 5 U.S.C. 552b(c)(6).)

JOSEPH A. SANCHES,
Advisory Committee
Management Officer.

DECEMBER 15, 1978.

[FR Doc. 78-35538 Filed 12-21-78; 8:45 am]

[4410-01-M]

UNITED STATES CIRCUIT JUDGE NOMINATING COMMISSION; FOURTH CIRCUIT PANEL

Meeting

The first meeting of the nominating panel for the Fourth Circuit of the United States Circuit Judge Nominating Commission will be held on Monday, January 8, 1979, at 9:30 a.m., Federal Building, U.S. Court House, Richmond, Virginia. This meeting will be closed to the public pursuant to P.L. 92-463, Section 10(D) as amended. (CF 5 U.S.C. 552b(c)(6).)

JOSEPH A. SANCHES,
Advisory Committee
Management Officer.

DECEMBER 19, 1978.

[FR Doc. 78-35568 Filed 12-21-78; 8:45 am]

[4410-18-M]

Law Enforcement Assistance Administration

NATIONAL MINORITY ADVISORY COUNCIL ON CRIMINAL JUSTICE

Reestablishment

The Law Enforcement Assistance Administration (LEAA) hereby determines that the reestablishment of the National Minority Advisory Council on Criminal Justice (NMACCJ) is in the public interest and necessary, appropriated and consistent with the purposes of the Federal Advisory Committee Act, Pub. 92-463, LEAA Instruction I 2100.1, and Office of Management and Budget Circular A-63. Although Determination was made previously, LEAA failed to publish notice of reestablishment.

1. Designation: The Committee shall be known as the National Minority Advisory Committee on Criminal Justice (NMAC).

2. Purpose: To advise LEAA on the needs and views of the Nation's minority communities as they relate to LEAA's priorities and policies relating to the improvement of law enforcement and criminal justice.

3. Reestablishment date and termination date: The Committee will remain in existence for six months from the date of its reestablishment, from June 30, 1978 through December

31, 1978 or until superceded by federal legislation prior to that date.

4. Meetings: The Committee will meet quarterly, or more frequently as required to carry out its purposes and fulfill its duties.

5. Membership: Membership of the Council and its committees will be drawn from concerned Federal agencies, public law enforcement agencies, private businesses, social agencies, institutions and representatives from the minority groups designated by 28 CFR 42.301 Subpart E.

6. Authority: The Council will operate pursuant to the provisions of the Federal Advisory Committee Act, Pub. L. 92-463, OMB Circular No. A-63, LEAA Instruction I 2100.1, and any additional orders and directives issued in implementation of the act.

HENRY S. DOGIN,
Deputy Administrator
for Policy Development.

(FR Doc. 78-35572 Filed 12-21-78; 8:45 am)

[4510-29-M]

[4830-01-M]

DEPARTMENT OF LABOR

Pension and Welfare Benefit Programs

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Class Exemption for Certain Transactions Involving Insurance Company Pooled Separate Accounts (Prohibited Transaction Exemption 78-19)

AGENCIES: Department of Labor, Department of the Treasury, Internal Revenue Service.

ACTION: Grant of class exemption.

SUMMARY: This exemption allows insurance company pooled separate accounts, in which employee benefit plans have an interest, to engage in certain transactions, provided specified conditions are met. The exemption also enables an employee benefit plan to hold, under certain circumstances, employer securities or employer real property. In the absence of this exemption, these insurance company pooled separate account transactions and employee benefit plan holding might be prohibited by the Employee Retirement Income Security Act of 1974 (hereinafter the Act or ERISA) and the Internal Revenue Code of 1954 (hereinafter the Code).

EFFECTIVE DATE: January 1, 1975.

FOR FURTHER INFORMATION CONTACT:

Alan Levitas, Office of Fiduciary Standards, Division of Exemptions, Pension and Welfare Benefit Programs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210, (202) 523-8884. This not a toll free number.

SUPPLEMENTARY INFORMATION: On October 11, 1977 notice was published in the FEDERAL REGISTER (42 FR 54886) that the Department of Labor and the Internal Revenue Service (hereinafter collectively referred to as the Agencies) had under consideration a proposed class exemption from the restrictions of sections 406 and 407(a) of ERISA and from the taxes imposed by sections 4975(a) and (b) of the Code, by reason of section 4975(c)(1) of the Code. The proposed class exemption was requested in an application (No. D-039) filed by the American Council of Life Insurance, the Prudential Life Insurance Co. of America, The Equitable Life Assurance Society of the United States, the John Hancock Mutual Life Insurance Co., and Connecticut General Life Insurance Co. (hereinafter collectively referred to as the Applicants), and would exempt certain transactions entered into by insurance company separate accounts in which employee benefit plans invest. The exemption was proposed and public comments were received in accordance with the procedures set forth in ERISA Procedure 75-1 (40 FR 18471, April 28, 1975) and Rev. Proc. 75-26, 1975-1 C.B. 722. Notice of a public hearing on the proposed exemption was published on December 30, 1977 (42 FR 65308) and the public hearing was held on February 3, 1978.

In response to the comments and testimony received, the Agencies have amended certain provisions of the exemption. The format of the exemption, however, remains unchanged. In section I, the Agencies set out a general exemption and then list three situations in which relief will be available even though the terms of the general exemption are not met. Section II includes exemptions, with requirements independent of those contained in section I, which are applicable to specific types of transactions. Discussed below are the exemption's major provisions and the Agencies' responses to comments they received.

I. OUTLINE OF THE EXEMPTION

A. THE SECTION I PROVISIONS

Section I(a), the exemption's basic provision, permits a pooled separate account to engage in transactions, which otherwise might be prohibited by sections 406 and 407(a) of the Act and section 4975(c)(1) of the Code, with persons who are parties in interest with respect to plan¹, so long as the plan's participation does not exceed a specified percentage of the total assets in the pooled separate account. A transaction between an employer of employees covered under a

plan and an insurance company pooled separate account in which the plan has an interest greater than that indicated in section I(a) may nonetheless be exempt provided other conditions, listed in section I(b) of the exemption, are met. If a plan complies with the requirements of either section I(a) or section I(b), section I(c) of the exemption allows the plan under certain circumstances to acquire or hold qualifying employer securities or qualifying employer real property in excess of the 10 percent limitation of section 407(a) of the Act. Section I(d) of the exemption enables insurance company pooled separate accounts to acquire or hold employer securities or employer real property in certain situations in which the requirements of sections I(a) or I(b) are not met.

B. THE SECTION II EXEMPTIONS

The four exemptions contained in section II cover specific transactions which may be entered into by pooled separate accounts. Under paragraph (a) of section II, a party in interest with respect to a plan is permitted in certain cases to furnish goods to an insurance company pooled separate account in which the plan has an interest exceeding the section I limits. Section II(a) also allows both the leasing of real property and the incidental furnishing of goods by a pooled separate account to a party in interest, provided specified conditions are fulfilled. Section II(b) enables a pooled separate account to engage in certain transactions with individuals who are parties in interest by virtue of being service providers. Section II(c) allows an insurance company or its affiliate to provide a pooled separate account, maintained by that company, with real property investment management services, so long as those services are provided at cost. The fourth exemption contained in section II, which was added in response to comments received by the Agencies, specifically allows certain transactions involving places of public accommodation.

C. GENERAL CONDITIONS

All of the provisions in section I and II are subject to conditions, set out in section III, which are designed to further safeguard against abuses. Section III requires each exempted transaction to be at least as favorable to the pooled separate account as an arm's-length transaction with an unrelated party would be. In addition, the insurance company maintaining the separate account must keep a record of every exempted transaction for a period of six years after that transaction occurs. The recorded information is available for inspection by those individuals described in section III(c) of the exemption.

¹As used herein the term "party in interest" includes persons who are "disqualified persons" within the meaning of section 4975(e)(2) of the Code.

II. DISCUSSION OF COMMENTS RECEIVED

A. REDEFINING EMPLOYER SECURITIES AND EMPLOYER

Real Property

Comments were received urging the Agencies to define more broadly the terms "employer securities" and "employer real property" to cover securities or real property of certain partnerships, joint ventures or corporations, which are not "affiliates" under section 407(d)(7) of the Act, but which are parties in interest with respect to a plan investing in the separate account under sections 3(14) (E), (G), (H), and (I) of the Act because of some relationship to an employer. Thus, it was requested, in effect, that the following persons be deemed employers for purposes of the exemption: (1) 50 percent owners of the employers; (2) business entities 50 percent or more owned by the employer; (3) employees, officers, directors or 10 percent shareholders of the employer or of those persons described in (1) and (2); and (4) 10 percent or more partners or joint venturers in the employer or in the persons described in (1) and (2).

Section I(d) of the exemption has been modified to include the relief requested. This section reflects the position that a pooled separate account should be allowed, in certain situations, to acquire, sell or hold employer securities or to acquire, sell, hold or lease employer real property, even though the plan's interest in the pooled separate account should not be deemed *de minimus*. If a pooled separate account can enter into certain transactions involving employer securities or employer real property, it should also be allowed to engage in similar transactions involving securities issued by, or real property leased to, persons who are parties in interest by virtue of their relationship to the employer, and who are presumably less able, than an employer of employees covered by a plan, to influence the investment decisions of a separate account in which the plan has an interest.

B. PUBLICLY ISSUED OR TRADED DEBT INSTRUMENT EXEMPTION

Section I(d), as proposed, included a condition which, if applicable, would have required that, immediately after a separate account's acquisition of an obligation, at least 50 percent of the aggregate amount of the issue outstanding at the time of the acquisition be held by persons independent of the issuer. Comments were received requesting the Agencies to make this condition inapplicable to acquisitions of publicly issued or traded instruments.² The Applicants stated that or-

dinarily such instruments would comply with section I(d)'s 50 percent requirement. However, the Applicants argued, to prove that this requirement was met would be unnecessarily difficult and expensive, since the identities of the persons holding publicly issued or traded debt instruments are almost always unknown to, and not readily ascertainable by, an insurance company.

In response to this argument, the Agencies have redrafted section I(d) to make the 50 percent test applicable only to those securities that qualify as "restricted securities" as that term is defined in Rule 144 under the Securities Act of 1933.³ The Agencies have concluded that for securities falling outside the "restricted securities" category, inquiry into and proof of compliance with the 50 percent requirement of section I(d) would be comparatively too time consuming and expensive for the benefit which might be obtained. On the other hand, it appears that relatively little burden is involved in ascertaining the ownership of restricted securities and the proportion of such securities held by the separate account.

C. SECTION I(D) AND THE ACQUISITION OF EMPLOYER STOCK

The Applicants requested that section I(d) be extended to cover acquisition of employer stock. The Agencies have adopted this suggestion.

D. MAKING SECTION I(D) APPLICABLE TO SALES AND LEASES

Section I(d) of the proposed exemption can be read as being applicable to only the acquisition or holding of employer real property. The Agencies have modified the exemption to make explicit that it applies to the execution of a lease involving real property.

The Agencies have also adopted the Applicants' suggestion that section I(d) be extended to cover sales of employer securities and employer oral property. This action was taken to

obligation which is traded on a national securities exchange or in the over-the-counter market, or which has a maturity at the time of issuance not in excess of nine months. This definition, in essence, excludes only private placement obligations with a maturity in excess of nine months.

³"Restricted securities" are defined in Rule 144 as "securities acquired directly or indirectly from the issuer thereof, or from an affiliate of such issuer, in a transaction or chain of transactions not involving any public offering or from the issuer in a transaction in reliance on Rule 240 under the Securities Act of 1933 or which were issued by an issuer in a transaction in reliance on Rule 240 and were acquired in a transaction or chain of transactions not involving any public offering." Rule 240 provides an exemption from registration under the Act for certain limited offers and sales by closely held issuers if the terms and conditions of the rule are met.

conform the class exemption to section 408(e) of the Act, upon which the exemption was in large part modeled.⁴

E. VALUE LIMITS OF THE SMALL LEASE AND GOODS EXEMPTION

Section II(a) of the exemption permits a pooled separate account to engage in a transaction, involving the furnishing of goods in connection with real property, with persons who are parties in interest, so long as the amount involved in the transaction does not exceed a specified amount. That amount in any year is the greater of \$25,000 or .025 percent of the fair market value of the assets of the pooled separate account on the account's most recent valuation date prior to the transaction. The exemption requires all transactions between a pooled separate account and a particular party in interest to be aggregated to determine whether these limits are exceeded.

In their comments, the Applicants requested the Agencies to redraft section II(a) to require only that the amount of each transaction, and not the aggregate amount of all transactions, between a pooled separate account and a party in interest not exceed in any year \$25,000 or .025 percent of the fair market value of the account's assets.⁵ The applicant argued that a transaction by transaction test is appropriate, in part, because the individuals responsible for the leasing and management of the buildings to which section II(a) would apply, are local or regional managers and not officials of the insurance company's central office. Moreover, the Applicants argued, insurance companies would have difficulty administering section II(a)'s aggregate amount test.

The Agencies have not adopted the Applicants' proposed transaction by transaction test. The Agencies agree with the Applicants that the \$25,000 or .025 percent test contained in the proposed exemption will require centralized recordkeeping by the insurance company sponsor of the separate account and that this standard will

⁴Section 408(e) requires, generally, that an acquisition, sale or lease must be for adequate consideration. This condition need not be incorporated into this exemption, because, as mentioned in the text above, section III of the exemption requires any transaction to be on terms at least as favorable to a pooled separate account as an arm's-length transaction with an unrelated third party.

⁵The effect of the section II(a) test, as proposed, is to provide that if a separate account's assets invested in real property do not exceed \$100 million, then the separate account and a party in interest can enter into transactions which do not exceed the aggregate amount of \$25,000 per year. But if the assets of the separate account exceed \$100 million, then the .025 percent test must be met.

²At the hearing the Applicants defined a publicly issued or traded instrument as an

limit the availability of the exemption for certain of the largest separate accounts. Nevertheless, the Agencies believe that the Applicants' proposed test would be open-ended since it would permit a pooled separate account to enter into an unlimited number of leases in the amount of \$25,000 or less, so long as each lease involved separate property. Thus, the modification suggested by the Applicants, in the context of this class exemption, would not afford adequate safeguards. The Agencies would consider additional requests for exemption covering small leases and goods which incorporated a transaction by transaction test, yet contained adequate safeguards, perhaps in the form of an accompanying total asset test.

F. SEPARATE ACCOUNTS AND FURNISHING GOODS

Comments were received suggesting that section II(a) be clarified with respect to its applicability to transactions in which a separate account furnishes incidental goods to a party in interest in connection with a lease of property. For example, the Applicants questioned whether (a) a hotel owned by a separate account might serve meals to a guest or (b) a separate account, as lessor of a shopping center, might furnish cleaning supplies to tenants. In order to assure the Applicants that these types of transactions may continue under ERISA, the Agencies have adopted their suggestion.

G. EXEMPTION FROM SECTION 407(A) OF THE ACT

In their written comments, the Applicants asked that proposed section II(a) be amended to include an exemption from section 407(a) of the Act. The Applicants suggested that unless such relief were added, those leases covered by section II(a) would have to be counted as employer real property for purposes of section I(d) of the exemption. The effect of considering these leases to be employer real property, the Applicants argued, would be to place an undue recordkeeping burden on pooled separate accounts.

The Agencies have decided not to incorporate an exemption from section 407(a) of the Act into section II(a) largely because such a change would result in an overly broad exemption containing insufficient safeguards. It should be noted that leases between a separate account and an employer would be permissible under the section I (a) or (b) exemptions, and that these leases need not be counted as employer real property if the plan's participation in the separate account or the substantiality of the employer does not exceed the limits of the basic exemption. To emphasize section II(a)'s narrow scope, the Agencies have re-

vised that section to make clear that it gives no relief from the restriction of section 406(a)(1)(E) or section 406(a)(2) of the Act.

H. ACCESS TO RECORDS

Section III(c) of the exemption requires insurance company separate accounts to maintain record of transactions covered by the provisions of sections I and II and to make these records available to a number of individuals, including participants of plans investing in the separate account. The Applicants argued that giving all participants the unconditional right to examine a separate account's records will create a large potential for harassment and abuse. Consequently, the Applicants suggested that a procedure be established that would permit a separate account to decline temporarily to honor requests for examination of records by participants, beneficiaries, and their representatives where those requests are unduly burdensome.

The Agencies see no need to adopt the Applicant's suggested modification of section III(c). The operation of nearly identical recordkeeping requirements contained in other class exemptions has apparently not resulted in unduly burdensome requests. The mere possibility that the record-keeping procedure included in the exemption might create a potential for abuse is not a convincing reason for the Agencies to adopt an alternate provision at this time.

The Agencies have rewritten section III(c) to make clear that all those individuals who are authorized to examine insurance company records under the exemption are subject to the same limitations. The language that has been added is not intended to reflect any substantive change in the scope of the section III(c)'s access requirements from that described in the proposed exemption.

I. THE DEFINITION OF "AFFILIATE"

The Applicants suggested that the Agencies narrow the definition of "affiliate" for purposes of the exemption. The definition of that term contained in section IV(b) of the exemption is modeled after one used in the Investment Company Act of 1940 and is similar to those appearing in other class exemptions under ERISA.

(1) *Partners.* The Applicants argued that partners of life insurance companies should not be considered affiliates under the exemption. The Applicants contended that the result of including partners within the definition of an affiliate would be to make much of the exemption unavailable to separate accounts engaging in transactions involving partners. Typically, the Applicants stated, life insurance companies

engage in many dealings through partnerships and may have thousands of partners.

The Agencies have redrafted section IV(b)(2) to make clear their intent that the term "partner" in that section refer only to a partner in, and not to a partner with, an insurance company, insurance company pooled separate account or an employer of employees covered by a multiple employer plan. The persons identified as "affiliates" in section IV(b) are persons who are likely to share a strong identity of interest with those entities seeking to be covered by the exemption. Because of these shared interests, such persons may be unable to act impartially when engaging in transactions that could benefit the persons to whom they are related. On the other hand, a co-partner is unlikely to influence as significantly, or to be as significantly influenced by, a person with whom it is a partner as to other matters. Accordingly, a co-partner should not be deemed an affiliate for purposes of this exemption.

2. *Controlling and Controlled Persons.* Section IV(A)(1) of the exemption defines "affiliate" to include any person controlling, controlled by, or under common control with, the person. "Control" is defined as the power to exercise a controlling influence over the management or policies of a person. The Applicants argued that the definition of controlled and controlling person is inadequate because it is imprecise and must be applied to the facts and circumstances of each transaction entered into by a separate account. The Agencies believe that, in general, a test based on the facts of each individual transaction affords the greatest protection to employee benefit plans and their participants. In this connection it is noted that the controlling or controlled person test has been used successfully by the Agencies in other class exemptions.

3. *Officers, Directors and Employees.* The Applicants suggested that insurance company officers, directors and employees should be excluded from the definition of affiliate for the purposes of the small lease and goods exemption of section II(a). They argued that such a change was necessary and appropriate to allow such persons to stay, for example, at a hotel owned by the separate account. It is questionable that the approach suggested by the Applicants would successfully deal with a situation involving hotel accommodations, since the providing of lodging, as a technical matter, is more generally termed a license and not a lease. Moreover, defining "affiliate" in the way the Applicants suggest would make the section II(a) exemption applicable to a lease, involving separate

account assets, entered into by an insurance company officer who has significant influence over the separate account.

It does not appear likely that Congress intended ERISA to prevent an officer, director or employee of an insurance company, or a participant in a plan having an interest in a separate account maintained by that company, from staying or eating at a hotel owned by the separate account.* In order to avoid any possible confusion, the Agencies have added section II(d) to the exemption to permit transactions involving places of public accommodation so long as, and to the extent that, the services and facilities furnished to any party in interest are provided to the general public.

4. *Representatives.* Section IV(b)(1) of the proposed exemption included representatives of an insurance company within the definition of an affiliate. The Applicants, in their comments, noted that "representatives" is a broad term that might be construed to cover a number of persons who may take action on behalf of insurers such as banks, attorneys and real estate brokers.

The Agencies' intent in using the term "representative" was to ensure that insurance agents, who might not be considered common law employees, had to comply with the requirements of the class exemption. In view of this intent and in response to the Applicants' comments, the Agencies have deleted the word "representative" from section IV(b)(1) and have expressly provided that insurance agents are to be considered insurance company employees for the purposes of this exemption.

J. FRACTIONAL SHARES OF SEPARATE ACCOUNT ASSETS

Paragraph (d) of section I of the proposed exemption contained a provision stating that, for purposes of compliance with the conditions imposed by that paragraph, each plan shall be considered to own the same fractional share of each asset in the pooled separate account as its fractional share of total assets in the pooled separate account on the account's most recent preceding valuation date. The Agencies have renumbered this provision section IV(e)(ii) to make clear that it applies generally to the entire class exemption.

K. SHORT-TERM OBLIGATIONS EXEMPTION

At the hearing and in their post hearing submissions, the Applicants

took the position that the conditions of the class exemption should not apply to investments in short-term obligations. The Agencies believe that special treatment may be necessary for insurance company separate account investments in short-term securities. However, at this time, the Agencies cannot determine on the basis of the record whether or to what extent to grant such relief. Thus, in order not to delay the effectiveness of the other provisions of this exemption, no special treatment for short term obligations has been proposed or granted.⁷

L. UNION LABOR LIFE INSURANCE COMPANY COMMENTS

Union Labor Life Insurance Company filed comments requesting the Agencies' view of the applicability of the class exemption to a particular factual situation. The Agencies are considering these comments in connection with an individual exemption request⁸ submitted by Union Labor Life. GENERAL INFORMATION: The attention of interested persons is directed to the following: (1) The fact that a transaction is the subject of an exemption granted under section 408(a) of the Act and section 4975(c)(2) of the Code does not relieve a fiduciary or other party in interest with respect to a plan to which the exemption is applicable from certain other provisions of the Act and the Code, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of section 404 of the Act which, among other things, require a fiduciary to discharge his duties respecting the plan solely in the interest of the plan's participants and beneficiaries and in a prudent fashion in accordance with section 404(a)(1)(B) of the Act; nor does it affect the requirement of section 401(a) of the Code that a plan must operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) This exemption is supplemental to, and not in derogation of, any other provision of the Act and the Code, including statutory exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of whether the transaction is in fact a prohibited transaction.

⁷ Among other matters, the Agencies must consider whether appropriate relief would require distinguishing between accounts designed primarily to make such investments and other accounts. In this connection the Agencies recognize that class or individual applicants may wish, in the future, to submit applications concerning short-term investments by separate accounts.

⁸ Exemption Application No. D-1044.

(3) The class exemption is applicable to a particular transaction only if the transaction satisfies the conditions specified in the class exemption.

(4) This document does not meet the criteria for significant regulations set forth in paragraph 8 of the proposed Treasury directive appearing in the FEDERAL REGISTER for Wednesday, May 24, 1978 (43 FR 22319).

EXEMPTION

In accordance with section 408(a) of the Act and section 4975(c)(2) of the Code, and based upon the entire record including the written comments submitted in response to the notice of October 11, 1977, and the testimony given at the public hearing of February 3, 1978, the Department and the Service make the following determinations:

(a) The class exemption set forth herein is administratively feasible;

(b) It is in the interests of plans and of their participants and beneficiaries; and

(c) It is protective of the rights of participants and beneficiaries of plans.

Accordingly, the following exemption is hereby granted under the authority of section 408(a) of the Act and section 4975(c)(2) of the Code and in accordance with the procedures set forth in ERISA Procedure 75-1 and Rev. Proc. 75-26.

SECTION I—BASIC EXEMPTION

Effective January 1, 1975, the restrictions of sections 406(a), 406(b)(2) and 407(a) of the Act and the taxes imposed by section 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A), (B), (C), or (D) of the Code, shall not apply to transactions described below if the applicable conditions set forth in section III are met.

(a) *General exemption.* Any transaction between a party in interest with respect to a plan and an insurance company pooled separate account in which the plan has an interest, or any acquisition or holding by the pooled separate account of employer securities or employer real property, if at the time of the transaction, acquisition or holding—

(1) The assets of the plan (together with the assets of any other plans maintained by the same employer or employee organization) in the pooled separate account do not exceed—

(i) 10 percent of the total of all assets in the pooled separate account, if the transaction occurs prior to February 20, 1979; or

(ii) 5 percent of the total of all assets in the pooled separate account, if the transaction occurs on or after February 20, 1979, and

(2) The party in interest is not the insurance company which holds the plan assets in its pooled separate ac-

* For example in the conference report accompanying the Act, the conferees, when discussing a somewhat analogous situation, expressed the expectation that an ordinary "blind" transaction in securities on an exchange with a party in interest would not be a prohibited transaction. Conference Report on the Act, H.R. Rep. No. 93-1280, 93d Cong., 2d Sess. 307 (1974).

count, any other separate account of the insurance company, or any affiliate of the insurance company.

(b) *Multiple employer plans exemption.* Any transaction between an employer (or an affiliate of an employer) of employees covered by a multiple employer plan and an insurance company pooled separate account in which the plan has an interest, or any acquisition or holding by the pooled separate account of employer securities or employer real property, if at the time of the transaction, acquisition or holding—

(1) In the case of a transaction occurring prior to February 20, 1979, the employer is not a substantial employer with respect to the plan (within the meaning of section 4001(a)(2) of the Act); or

(2) In the case of a transaction occurring on or after February 20, 1979,

(i) The assets of the multiple employer plan in the pooled separate account do not exceed 10 percent of the total assets in the pooled separate account, and the employer is not a substantial employer with respect to the plan (within the meaning of section 4001(a)(2) of the Act), or

(ii) The assets of the multiple employer plan in the pooled separate account exceed 10 percent of the total assets in the pooled separate account, but the employer is not a substantial employer and would not be a substantial employer with respect to the plan within the meaning of section 4001(a)(2) of the Act if "5 percent" were substituted for "10 percent" in that definition.

(c) *Excess holdings exemption for employee benefit plans.*

Any acquisition or holding or qualifying employer securities or qualifying employer real property by a plan (other than through a pooled separate account) if—

(1) The acquisition or holding contravenes the restrictions of sections 406(a)(1)(E), 406(a)(2) and 407(a) of the Act solely by reason of being aggregated with employer securities or employer real property held by an insurance company pooled separate account in which the plan has an interest, and

(2) The requirements of either paragraph (a) or paragraph (b) of this section are met.

(d) *Employer securities and employer real property.*

(1) Except as provided in subsection 2 of the paragraph, any acquisition, sale or holding of employer securities and any acquisition, sale, holding or lease of employer real property by the insurance company pooled separate account in which a plan has an interest and which does not meet the requirements of paragraphs (a) or (b) of this section, if no commission is paid to the

insurance company or to the employer or any affiliate of the employer in connection with the acquisition or sale of employer securities or the acquisition, sale or lease of employer real property, and—

(i) In the case of employer real property—

(a) Each parcel of employer real property and the improvements thereon held by the pooled separate account are suitable (or adaptable without excessive cost) for use by different tenants, and

(b) The property of the pooled separate account, which is leased or held for lease to others, in the aggregate, is dispersed geographically.

(ii) In the case of employer securities—

The employer security is (1) stock, or (2) a bond, debenture, note, certificate, or other evidence of indebtedness (the security described in (2) is hereinafter referred to as an "obligation"), and

(b) The insurance company in whose pooled separate account the security is held is not an affiliate of the issuer of the security and, if the security is an obligation of the issuer, either

(c) The pooled separate account already owns the obligation at the time the plan acquires an interest in the separate account and interests in the pooled separate account are offered and redeemed in accordance with valuation procedures of the pooled separate account applied on a uniform or consistent basis, or

(d) Immediately after acquisition of the obligation: (1) not more than 25 percent of the aggregate amount of obligations issued in the issue and outstanding at the time of acquisition is held by such plan, and (2) in the case of an obligation which is a restricted security within the meaning of Rule 144 under the Securities Act of 1933, at least 50 percent of the aggregate amount referred to in (1) is held by persons independent of the issuer. The insurance company, its affiliates and any separate account of the insurance company shall be considered persons independent of the issuer if the insurance company is not an affiliate of the issuer.

(2) Provided that, in the case of a plan which is not an eligible individual account plan (as defined in section 407(d)(3) of the Act), immediately after such acquisition the aggregate fair market value of employer securities and employer real property owned by the plan does not exceed 10 percent of the fair market value of the assets of the plan.

(3) For the purposes of the exemption contained in subsection (1) of this paragraph (d), the term "employer securities" shall include securities issued by, and the term "employer real prop-

erty" shall include real property leased to, a person who is a party in interest with respect to a plan (which has an interest in the separate account) by reason of a relationship to the employer described in section 3(14)(E), (G), (H), or (I) of the Act.

SECTION II—SPECIFIC EXEMPTIONS.

Effective January 1, 1975, the restrictions of sections 406(a)(1)(A), (B), (C), and (D), and 406(b)(1) and (2) of the Act and the taxes imposed by sections 4975(a) and (b) of the Code by reason of section 4975(c)(1)(A), (B), (C), (D) or (E) of the Code shall not apply to the transactions described below provided that the conditions of section III are met.

(a) *Certain leases and goods.* The furnishing of goods to an insurance company pooled separate account by a party in interest with respect to the plan, which plan has an interest in the pooled separate account, or the leasing of real property of the pooled separate account to a party in interest and the incidental furnishing of goods to the party in interest by the insurance company separate account, if—

(1) In the case of goods, they are furnished to or by the pooled separate account in connection with the real property investments of the pooled separate account;

(2) The party in interest is not the insurance company, any other pooled separate account of the insurance company, or an affiliate of the insurance company; and

(3) The amount involved in the furnishing of goods or leasing of real property in any calendar year (including the amount under any other lease or arrangement for the furnishing of goods in connection with the real property investments of the pooled separate account with the same party in interest, or any affiliate thereof) does not exceed the greater of \$25,000 or .025 percent of the fair market value of the assets of the pooled separate account on the most recent valuation date of the account prior to the transaction.

(b) *Transactions with persons who are parties in interest to the plan solely by virtue of being certain service providers or certain affiliates of service providers.* Any transaction between an insurance company pooled separate account and a person who is a party in interest with respect to a plan, which plan has an interest in the pooled separate account, if—

(1) The person is a party in interest including a fiduciary by reason of providing services to the plan, or by reason of a relationship to a service provider described in section 3(14) (F), (G), (H), or (I) of the Act, and the person exercised no discretionary authority, control, responsibility, or in-

fluence with respect to the investment of plan assets in the pooled separate account and has no discretionary authority, control, responsibility, or influence with respect to the management or disposition of the plan assets held in the pooled separate account; and

(2) The person is not an affiliate of the insurance company.

(c) *Management of Real Property.* Any services provided to an insurance company pooled separate account (in which a plan has an interest) by the insurance company or its affiliate in connection with the management of the real property investments of the pooled separate account, if the compensation paid to the insurance company or its affiliate for the services does not exceed the cost of the services to the insurance company or its affiliate.

(d) *Transactions involving places of public accommodation.* The furnishing of services, facilities and any goods incidental to such services and facilities by a place of public accommodation owned by an insurance company pooled separate account, to a party in interest with respect to a plan, which plan has an interest in the pooled separate account, if the services, facilities and incidental goods are furnished on a comparable basis to the general public.

SECTION III—GENERAL CONDITIONS

(a) At the time the transaction is entered into, and at the time of any subsequent renewal thereof that requires the consent of the insurance company, the terms of the transaction are not less favorable to the pooled separate account than the terms generally available in arm's-length transactions between unrelated parties.

(b) The insurance company maintains for a period of six years from the date of the transaction the records necessary to enable the persons described in paragraph (c) of this section to determine whether the conditions of this exemption have been met, except that (1) a prohibited transaction will not be deemed to have occurred if, due to circumstances beyond the control of the insurance company, the records are lost or destroyed prior to the end of the six-year period, and (2) no party in interest shall be subject to the civil penalty which may be assessed under section 502(i) of the Act, or to the taxes imposed by section 4975 (a) and (b) of the Code, if the records are not maintained, or are not available for examination as required by paragraph (c) below.

(c)(1) Except as provided in subsection 2 of this paragraph and notwithstanding any provisions of subsections (a)(2) and (b) of section 504 of the Act, the records referred to in paragraph

(b) of this section are unconditionally available at their customary location for examination during normal business hours by:

(i) Any duly authorized employee or representative of the Department of Labor or the Internal Revenue Service,

(ii) Any fiduciary of a plan who has authority to acquire or dispose of the interests of the plan in the separate account, or any duly authorized employee or representative of such fiduciary,

(iii) Any contributing employer to any plan which has an interest in the pooled separate account or any duly authorized employee or representative of that employer,

(iv) Any participant or beneficiary of any plan which has an interest in the pooled separate account or any duly authorized employee or representative of such participant or beneficiary.

(2) None of the persons described in subparagraphs (i) through (iv) of this paragraph shall be authorized to examine an insurance company's trade secrets or commercial or financial information which is privileged or confidential.

SECTION IV—DEFINITIONS AND GENERAL RULES

For purposes of sections I through III above.

(a) The term "multiple employer plan" means an employee plan which satisfies at least the requirements of section 3(37)(A)(i), (ii) and (v) of the Act and section 414(f)(1)(A), (B), and (E) of the Code.

(b) An "affiliate" of a person includes—

(1) Any person directly or indirectly, through one or more intermediaries, controlling, controlled by, or under common control with the person;

(2) Any officer, director, employee (including, in the case of an insurance company, an insurance agent thereof, whether or not the agent is a common law employee of the insurance company), or relative of, or partner in, any such person; and (3) Any corporation or partnership of which such person is an officer, director, partner, or employee.

(c) The term "control" means the power to exercise a controlling influence over the management or policies of a person other than an individual.

(d) The term "relative" means a "relative" as that term is defined in section 3(15) of the Act (or a "member of the family" as that term is defined in section 4975(e)(6) of the Code), or a brother, a sister, or a spouse of a brother or sister.

(e) *General.* (i) The time as of which any transaction, acquisition, or holding occurs for purposes of this exemption is the date upon which the trans-

action is entered into (or the acquisition is made) and the holding commences. Thus, for purposes of this exemption, if any transaction is entered into, or an acquisition is made, on or after January 1, 1975, or a renewal which requires the consent of the insurance company occurs on or after January 1, 1975, and the requirements of this exemption are satisfied at the time the transaction is entered into or renewed, respectively, or at the time the acquisition is made, the requirements will continue to be satisfied thereafter with respect to the transaction or acquisition and the exemption shall apply thereafter to the continued holding of the securities or property so acquired. This exemption also applies to any transaction or acquisition entered into, or holding commencing, prior to January 1, 1975, if either the requirements of this exemption would have been satisfied on the date the transaction was entered into or acquisition was made (or on which the holding commenced), or the requirements would have been satisfied on January 1, 1975 if the transaction had been entered into, acquisition was made, or if the holding had commenced, on January 1, 1975. Notwithstanding the foregoing, this exemption shall cease to apply to a holding exempt by virtue of section I(a) above at such time as the interest of the plan in the pooled separate account exceeds the percentage interest limitation of section I(a), if the excess results solely from an increase in the amount of consideration allocated to the pooled separate account by the plan. (ii) Each plan shall be considered to own the same fractional share of each asset (or portion thereof) in the pooled separate account as its fractional share of total assets in the pooled separate account on the most recent preceding valuation date of the account.

Signed at Washington, D.C., this 14th day of December, 1978.

IAN D. LANOFF,
Administrator of Pension and
Welfare Benefit Programs,
Labor-Management Services
Administration, U.S. Department
of Labor.

TED R. KERN,
Deputy Assistant Commissioner,
(Employee Plans and Exempt
Organizations), Internal Revenue
Service.

[FR Doc. 78-35282 Filed 12-15-78; 11:42 am]

[4510-43-M]

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[Docket No. M-78-77-C]

BURNRITE COAL CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted the petition (43 FR 30370) of Burnrite Coal Company to modify the application of 30 CFR 75.301 to its No. 3 Lykens Slope Mine located in Ashland County, Pa., in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that an alternative method exists that will guarantee at all times no less than the same measure of protection given miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The quantity of air in the working faces and in the last open crosscut was found to be in excess of the minimum requirements of 30 CFR 75.301.

2. Ventilation violation records revealed that the mine had been in compliance with air quantity requirements since its activation in June 1977, and that a hazardous condition due to methane, carbon dioxide, and other noxious or poisonous gases had not been detected since its opening.

3. Air sample analyses records and frequent onsite sampling confirm that harmful quantities of methane have not been detected in this mine.

4. The operator's records, as well as MSHA's, confirm that there were no ignitions, explosions, or mine fires in this mine since activation of the mine.

5. Air sample analyses records and frequent onsite sampling indicate that harmful quantities of carbon dioxide and other noxious or poisonous gases are not present in this mine.

6. Respirable dust was not found to be in excess of the maximum standards as verified by dust sample records, which revealed an average concentration of 0.13 mg/m³, and which was well below the present maximum standard of 2.0 mg/m³. A high of 1.5 milligrams was recorded on an operator cycle of ten samples collected when the maximum limit was 20 milligrams. As regards dust concentrations in anthracite mines, we point out that respirable dust data collected when a representative mine was regulated to simulate conditions with air quantities requested for this mine, revealed that there was no appreciable increase in dust concentrations with these smaller air quantities.

7. The operator contends that extremely high air velocities in restricted airways and manways present a very dangerous flying object hazard to the miners. Investigation has revealed that these conditions do not exist in this mine, consequently; we do not agree that this is a problem in the mine.

8. The operator argues that high velocities and large air quantities cause extremely uncomfortable damp and cold conditions in the already uncomfortable cold mine. This investigation tends to substantiate this claim even though the investigation was conducted during the warmer months. This mine is wet, consequently, a damp atmosphere is ever present. This dampness coupled with the cold air induced into the mine during the winter months creates an unbearable damp, cold working environment. The induced cold surface air does not have a chance to adjust substantially upwards due to the fact that the mine is shallow and small, and air travel distance and time required to deliver the air to the working area is short.

9. Interviews with the miners also substantiated Petitioner's claim that the mine conditions caused in part by compliance with 30 CFR 75.301 contribute to difficulty in attracting and retaining mine employees.

10. MSHA investigators also found there was no electric face equipment or other electrically operated mechanical mining equipment used in this mine, thus further minimizing any need for the quantities of air required by 30 CFR 75.301. The investigators concurred with the Petitioner in that the modification of the standard would in no way provide less than the same measure of protection afforded the miners under 30 CFR 75.301, and recommended the petition be granted.

Because of these findings, the Administrator for Coal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted, conditioned upon compliance with the following:

That Section 75.301 of the implementing regulations, 30 CFR 75, be modified for the Burnrite Coal Company, No. 3 Lykens Slope Mine to require in part, the minimum quantity of air reaching each working face shall be 1,500 cubic feet a minute, the minimum quantity of air reaching that last open crosscut in any pair or set of developing entries and the last open crosscut in any pair or set of rooms shall be 5,000 cubic feet a minute, and/or whatever additional quantity of air that may be required in any of these areas to maintain a safe and healthful atmosphere.

A copy of the decision is available for inspection by the public at the

Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 13, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35500 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-27-M]

EMERALD SLATE CORP.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 24146) of Emerald Slate Corp., to modify the application of 30 CFR 57.19-7 to its Emerald Slate Corp. Mine located in Northampton County, Pa., in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that the application of the standard to the mine will result in a diminution of safety to the miners of the mine.

MSHA based its determination on the following findings:

1. The petitioner has established that absence of overspeed and overtravel devices on the subject hoists would not result in a diminution of safety to the miners of the subject mine.

2. The sudden stop of the man-hoisting conveyance by a "dead-man" switch or other mechanical device could create an unnecessary hazard.

During the investigation it was learned from studies by various governmental agencies and by private corporations (all well knowledgeable in this type of hoist), that it would not be advisable to enforce the use of these mechanical devices on the subject hoists stipulated by the petitioner. A greater safety hazard or factor could be encountered if the mandatory safety standard 57.19-7 was enforced on this type of operation.

3. It is recommended that the modification be granted subject to the following conditions:

a. A stand-by hoistman is to be present at all times when man trips are made. The signature of the stand-by hoistman is to be in the hoist logbook along with the regular hoistman's signature.

b. A signalman (motioner) is to be present at all times during man trips, positioned to have visual capability throughout the trip, and to have communications with the hoistman at all times.

c. Quarry work area communications with the hoistman to be applicable at all times.

4. All the above recommendations are presently in effect and have been for the past four years. Granting of this modification to mandatory safety standard 5719-7 is contingent with the continuation of these three conditions and subject to review and revocation annually.

Because of these findings, the Administrator for Metal and Nonmetal Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 12, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35501 Filed 12-21-78; 8:45 am]

[4510-4-M]

[Docket No. M-78-29-M]

HECLA MINING CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 24148) of Hecla Mining Company to modify the application of 30 CFR 57.19-71 to its Lucky Friday Mine located in Mullan County, Idaho, in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that an alternative method exists that will guarantee at all times no less than the same measure of protection given miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The petitioner has established that a bucket partially filled with muck would provide a safer means of transportation for men engaged in the mucking cycle of the shaft-sinking operation than by having men riding in an empty bucket as required by 30 CFR 57.19-71.

2. During MSHA's investigation it was established that a platform suspended from the rim of the shaft muck bucket was used when in the normal timbering, drilling and blast cycles. This platform permitted ready access to the shaft bell signal cable and provided stable footing when riding in the muck bucket. It was also established that miners riding in the empty shaft bucket were unable to

reach the shaft bell signal cable and that the procedure of partially filling the muck bucket was primarily to overcome this problem.

The investigation concluded that safety of miners would not be diminished if the shaft-sinking muck bucket was partially filled, to allow safe means of reach to the shaft bell signal cable, during the mucking cycle.

3. The petitioner has established that modification of the application of 30 CFR 57.19-71 would not lessen the degree of safety afforded shaft crews, immediate supervisors and emergency personnel.

Because of these findings, the Administrator for Metal and Nonmetal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted, as it pertains to partially filling the shaft-sinking bucket during the mucking cycle. The modification is to exclude all other than the shaft crew, immediate supervisors, emergency and inspection personnel and be limited to the muck cycle of the shaft-sinking operation.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
Assistant Secretary,
for Mine Safety and Health.

[FR Doc. 78-35502 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-77-2]

HIGHWALL COAL CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

Notice is hereby given that the Mine Safety and Health Administration (MSHA) has granted the petition (41 FR 54248) of Highwall Coal Company to modify the application of 30 CFR 75.1405 to its No. 1 Mine located in Blount County, Alabama, in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. It has been determined that an alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard.

This determination was based on the following findings made by MSHA:

(1) The Highwall Mine is operated near Trafford, Jefferson County, Alabama. One section was operated in the Black Creek coal seam, which averages

22 inches. At the time, 26 men were employed and produced average of 60 tons of coal a day. The coal was hand-loaded from the face into chain conveyors, which was dumped into track mounted haulage cars.

(1) Haulage cars with a capacity of 1½ tons of coal were pulled or towed by mules over a 40 lb/yd rail track with a 36 inch gage. The distance from the face to the outside where the cars were dumped was approximately 2600 feet. The haulage cars are regularly coupled and uncoupled at chain conveyor dumping points and outside where the cars were dumped.

(3) The haulage cars had been modified to allow a person to uncouple cars by the use of an uncoupling bar attached to the coupling pin by a chain. The coupling link occasionally must be aligned to couple with other cars by the use of a link aligner which allows the person to control the coupling link without the necessity of going between the cars. The track curvature and undulating bottom make it necessary that the coupling link used between cars be free to move vertically over a wide range of track variations. This vertical tolerance necessary for movement of the coupling link makes use of the link aligner necessary when cars are to be coupled by impact.

(4) Most coupling/uncoupling is done when the cars are uncoupled from the mules.

(5) The grades are near-level.

(6) The cars are light-weight and can easily be pushed by hand.

(7) The alternate method proposed to guarantee no less than the same measure of protection afforded the miners by Section 75.1405, 30 CFR 75, by Mr. John Calvert, operator of the Highwall Mine, would not require miners to go between the ends of haulage cars when coupling or uncoupling and when in motion or attached to a source of power. The uncoupling bar and link aligner would be used as described above the description of the modification of track haulage cars.

(8) The investigation included observation of mine haulage track, loading and dumping procedures, modification of equipment, coupling and uncoupling regularly at locations where required and discussed with persons engaged in the performance of work related with each of the above. The results of the investigation did not indicate that the proposed alternate method would be less safe. Therefore, we recommend that the Petition for Modification be granted.

Because of these findings, the Administrator for Coal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the

Office of Standard, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 12, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35503 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-28-M]

NATIONAL GYPSUM CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 22792) of the National Gypsum Company to modify the application of 30 CFR 55.9-88 to its Sun City Mine and Mill located in Barbour County, Kansas, in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that an alternative method exists that will guarantee no less than the same measure of protection given miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The petitioner has established that it would not be feasible to install ROPS on the 1974 Cline side dump truck, the subject of the petition.

2. During MSHA's investigation it was established that the trucks operate over a wide, well maintained level road bed that is provided with adequate berms. There are no drop-offs along the road. The roadway inside the mine is wide and level, and the back scaled clean of loose material.

3. The petitioner has established that modification of the application of 30 CFR 55.9-88 would not lessen the degree of safety afforded the operator of the 1974 Cline side dump truck.

Because of these findings, the Administrator for Metal and Nonmetal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted as it pertains to the 1974 Cline side dump truck.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35504 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-77-219]

ORCHARD COAL CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (42 FR 43681) of Orchard Coal Company, to modify the application of 30 CFR 75.301 to its Orchard Slope Mine located in Schuylkill County, Pa., in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that an alternative method exists that will guarantee at all times no less than the same measure of protection afforded miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The quantity of air in the working faces and in the last open crosscut was found to be in excess of the minimum requirements of 30 CFR 75.301.

2. Ventilation violation records revealed that the mine was not always in compliance with respect to the air quantity requirement in the face area. However, a hazardous condition due to methane, carbon dioxide, and other noxious or poisonous gases was not detected in the mine during the period of noncompliance.

3. Air sample analysis records and frequent onsite sampling confirm that harmful quantities of methane have not been detected in this mine.

4. The operator's records, as well as MSDHA's confirm that there were no ignitions, explosions, or mine fires in this mine since activation of the mine.

5. Air sample analysis records and frequent onsite sampling indicate that harmful quantities of carbon dioxide and other noxious or poisonous gases are not present in this mine.

6. Respirable dust was not found to be in excess of the maximum standards as verified by dust sample records, which revealed an average concentration of 0.20 mg/m³, and which was well below the present maximum standard of 2.0 mg/m³. A high of 1.8 milligrams was recorded on an operator cycle of ten samples collected when the maximum limit was 20 milligrams. As regards dust concentrations in anthracite mines, we point out that respirable dust data collected when a representative mine was regulated to simulate conditions with air quantities requested for this mine, revealed that there was no appreciable increase in dust concentrations with these smaller air quantities.

7. The operator contends that extremely high air velocities in restricted airways and manways present a very dangerous flying object hazard to the

miners. Investigation has revealed that these conditions do not exist in this mine; consequently, we do not agree that this is a problem in the mine.

8. The operator argues that high velocities and large air quantities cause extremely uncomfortable damp and cold conditions in the already uncomfortable cold mine. This investigation tends to substantiate this claim even though the investigation was conducted during the warmer months. The mine is wet; consequently, a damp atmosphere is ever present. This dampness coupled with the cold air induced into the mine during the winter months creates an unbearable damp, cold working environment. The induced cold surface air does not have a chance to adjust substantially upwards due to the fact that the mine is shallow and small, and air travel distance and time required to deliver the air to the working area is short.

9. Interviews with the miners also substantiated petitioner's claim that the mine conditions caused in part by compliance with 30 CFR 75.301 contribute to difficulty in attracting and retaining mine employees.

10. MSHA investigators also found there was no electric face equipment or other electrically operated mechanical mining equipment used in this mine, thus further minimizing any need for the quantities of air required by 30 CFR 75.301.

Because of these findings, the Administrator for Coal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted, conditioned upon compliance with the following:

That § 75.301 of the implementing regulations, 30 CFR Part 75, be modified in part, the minimum quantity of air reaching each working face shall be 1,500 cubic feet a minute, the minimum quantity of air reaching the last open crosscut in any pair or set of developing entries and the last open crosscut in any pair or set of rooms shall be 5,000 cubic feet a minute, and/or whatever additional quantity of air that may be required in any of these areas to maintain a safe and healthful atmosphere.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 13, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35505 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-76-685]

PAGE FORK COAL COMPANY, INC.**Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard**

Notice is hereby given that the Mine Safety and Health Administration (MSHA), has granted in part the petition (41 FR 49548) of Page Fork Coal Company, Inc. to modify the application of 30 CFR 75.1710 to its No. 2 Mine located in Buchanan County, Virginia, in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. It has been determined that the application of such standard to such mine will result in a diminution of safety to the miners in such mine.

This determination was based on the following findings made by MSHA:

1. The No. 2 Mine was opened by three drifts into the Widow Kennedy Coalbed in June of 1976. The coalbed (normal mined) height varies from 45 to 57 inches locally. A total of five men, four underground, is employed on one active working section on one coal producing shift a day, five days a week. An average daily production of 100 tons of coal is loaded with a loading machine. Coal is transported from the face areas to the surface by battery powered tractor-trailers. At the present rate of production, the mine life expectancy is four years.

2. Self-propelled electric face equipment in the mine consists of one Model Mark IV Paul's Repair Shop Roof Bolting Machine, one Royal Cutting Machine, one Model 14BU7AE Joy Loading Machine, S.N. 8182, two Model MA-4 Epling Battery Tractors, S.N. GE575 purchased in March of 1974 and S.N. GE 2975 purchased in July of 1975.

3. A full bolting Roof Control Plan, utilizing 36-inch minimum length roof bolts on 4-foot centers crosswise and lengthwise, and been used in the 20-foot maximum width entries and crosscuts.

4. During the five months of operation, the mine has experienced no lost time injuries as a result of roof or rib falls. The mine has experienced no unintentional roof falls.

5. The height (floor to roof) varies from 45 to 57 inches.

6. Joy Loading Machine (Model 14BU7AE, S.N. 8182) is 37 inches high and was purchased in August of 1975.

Because of these findings, the MSHA Administrator, under authority delegated by the Secretary of Labor, ordered that the petition be denied as it pertains to the Paul Elswick Roof Bolting Machine, the Royal Cutting Machine and the two Epling battery-powered tractors, but granted as it

pertains to the 14BU Joy Loading Machine.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
*Assistant Secretary
for Mine Safety and Health.*

[FR Doc. 78-35506 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-100-C]

PYRO MINING COMPANY**Petition for Modification of Application of Mandatory Safety Standard**

Pyro Mining Company, Post Office Box 267, Sturgis, Kentucky 42459, has filed a petition to modify the application of 30 CFR 75.1710 (canopies) to its Wheatroft Mine in Webster County, Kentucky. The petition is filed under Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164.

The substance of the petition follows:

1. The petitioner is mining in heights averaging 40.3 inches.

2. The limestone roof of the mine averages six feet in thickness, and no roof falls have occurred in the mine.

3. When the petitioner has lowered canopies on electric face equipment to clear overhead obstructions, the limited space has forced equipment operators to lean outside the operator's compartment in order to operate the equipment.

4. These canopies have also impaired the equipment operator's field of vision.

5. For these reasons, the petitioner states that the use of cabs or canopies on electric face equipment in the mine results in a diminution of safety, and therefore the petitioner requests relief from the standard.

REQUEST FOR COMMENTS

Persons interested in this petition may furnish written comments on or before January 22, 1979. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
*Assistant Secretary
for Mine Safety and Health.*

[FR Doc. 78-35507 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-77-167]

SLAB FORK COAL CO.**Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard**

Notice is hereby given that the Mine Safety and Health Administration (MSHA) has granted in part the petition (42 FR 22423) of Slab Fork Coal Company to modify the application of 30 CFR 75.1405 to its Slab Fork No. 8 mine located in Wyoming County, West Virginia, in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. It has been determined that an alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard.

This determination was based on the following findings made by MSHA:

1. The Slab Fork No. 8 mine located in Slab Fork, West Virginia, is entered through two shafts, four slopes, and two drifts into the Pocahontas No. 4 coal bed, which averages 32 inches in thickness locally. A total of 182 men, 150 underground and 32 surface, is employed on two coal producing shifts, a day, five days a week. The daily production averages 600 tons of coal, all loaded mechanically, from four active producing sections.

2. Supplies for this mine are received at two separate locations or portals. One is called the "Slab Fork Portal" and the other is called the "Tams Portal".

3. The "Slab Fork Portal" is a slope entry and consists of a hoist, and mine track used to raise and lower the supply cars in and out of the mine. Due to the limited amount of area involved around the portal in relation to the supply yard area only two cars at a time can be hoisted and then shifted to be loaded with mine supplies. After these cars are loaded on the surface, they are then shifted out and lowered back into the mine and set on side tracks.

4. The "Tams Portal" is a drift portal where the supply cars are brought to the surface to be loaded with supplies. The area involved will accommodate four cars, then they must be switched out and more cars brought outside for more supplies.

5. After the supply cars are loaded from both the "Slab Fork Portal" and the "Tams Portal", they are transported either to side tracks in the mine or to the section supply areas.

6. The method used to transport these cars consists of usually 10 to 15 ton locomotives, one on each end of a trip. The mine track system that these cars and locomotives travel on consist of a 550 volt direct-current trolley circuit using 70-pound steel.

7. The supply cars are placed at each section belthead where the supplies are then unloaded for use on the coal producing sections. The cars are switched in and out of these areas usually one at a time and then put back into a train of cars to be sent back later to one of the portals for reloading.

8. During this investigation a cycle of switching the cars in and out of a section supply area was witnessed and the cars could be coupled and uncoupled with the use of the lever system proposed in this petition without the mine workers going between the supply cars.

9. The operator has elected to install automatic-type couplers on the rock cars involved in this petition.

Because of these findings, the MSHA Administrator, under authority delegated by the Secretary of Labor, ordered that the petition, as amended by withdrawal of the portion relevant to rock cars, be granted conditioned upon compliance with the provisions of the modification.

The modification is applicable only to mine cars used at the Slab Fork No. 8 Mine for the transportation of mine supplies.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35508 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-34-M]

STAUFFER CHEMICAL CO.

Final Action Granting a Petition for Modification Of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted the petition (43 FR 34550) of the Stauffer Chemical Company to modify the application of 30 CFR 57.21-46 to its Big Island Mine located in Sweetwater County, Wyoming, in accordance with

Section 101(c) of the Federal Mine Safety and Health Act of 1977, Public Law 95-164. MSHA has determined that an alternative method exists that will guarantee at all times no less than the same measure of protection given miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The Petitioner has established that the absence of crosscuts on the subject single entry decline would not result in a diminution of safety to the miners of the subject mine.

2. It is recommended that the modification be granted subject to the following conditions:

a. Ventilation shall be provided by using a permissible auxiliary fan capable of supplying 20,000 cfm of fresh air to the working face. The discharge end of the vent tubing shall not be more than 30-feet from the working face and the end of the tubing shall be so located that no dead air spaces can occur at the working face. Intake air to the auxiliary fan will be no less than 1½ times the rated capacity of the fan. These fans shall be inspected by competent persons at the start of each shift at least every three hours thereafter. Exhaust air shall be coursed directly into the returns.

b. The air quantity (cfm) and the methane concentration at the working face shall be checked every hour and the results recorded in an appropriate logbook, maintained specifically for these readings. The logbooks shall be readily available for the inspection by MSHA inspection personnel.

c. Roof control shall be provide by using 54-inch or longer by ¾-inch or longer roof bolts with 6 by 6-inch plates. Bolt spacing shall not exceed 48-inches center-to-center both lengthwise and crosswise. If fully-grouted resin bolts are used, the same spacing will be used and the bolt length will be 54-inches or longer. Construction mesh or wire mesh shall be installed as needed and additional supplementary roof support shall be installed as needed.

d. An approved, calibrated torque wrench that indicates the actual torque on the roof bolts shall be readily available at the working face. A minimum of 150-ft.-lbs. of torque shall be maintained on all mechanically-anchored roof bolts.

e. A qualified person shall torques on at least 25 percent of the roof bolts immediately after the working place has been fully bolted. At least once each week 10 percent or more of all roof bolts within 50-feet of the working face shall be spot-checked for proper torque.

f. All torque readings will be recorded in an appropriate logbook, showing the number of bolts tested and the torque readings. If a majority of the

installed torques are below 150-ft.-lbs. or above the recommended range for the bolts used, a review of the adequacy of the roof control procedures shall be made by an Authorized Representative of the Secretary.

g. No person shall work or travel beyond the last permanently installed roof support.

h. Information and mine map submitted on July 6, 1978, and now on file in the MSHA District Office, shall become a part of this modification.

Because of these findings, the Administrator for Metal and Nonmetal Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated December 14, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35509 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-21-M]

ALBION VEIN SLATE CO., INC.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 21747) of Albion Vein Slate Co., Inc. to modify the application of 30 CFR 57.19-7 to its Albion Vein Slate Quarry Mine located in Northampton County, Pa., in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164. MSHA has determined that the application of the standard to the mine will result in a diminution of safety to the miners of the mine.

MSHA based its determination on the following findings:

1. The petitioner has established that absence of overspeed and overtravel devices on the subject hoists would not result in a diminution of safety to the miners of the subject mine.

2. The sudden stop of the man-hoisting conveyance by a "dead-man" switch or other mechanical device could create an unnecessary hazard.

During the investigation it was learned from studies by various governmental agencies and by private corporations (all well knowledgeable in this type of hoist), that it would not

be advisable to enforce the use of these mechanical devices on the subject hoists stipulated by the petitioner. A greater safety hazard or factor could be encountered if the mandatory safety standard 57.19-7 was enforced on this type of operation.

3. It is recommended that the modification be granted subject to the following conditions:

a. A stand-by hoistman is to be present at all times when man trips are made. The signature of the stand-by hoistman is to be in the hoist logbook along with the regular hoistman's signature.

b. A signalman (motioner) is to be present at all times during man trips, positioned to have visual capability through the trip, and to have communications with the hoistman at all times.

c. Quarry work area communications with the hoistman to be applicable at all times.

4. All the above recommendations are presently in effect and have been for the past four years. Granting of this modification to mandatory safety standard 57.19-7 is contingent with the continuation of these three conditions and subject to review and revocation annually.

Because of these findings, the Administrator for Metal and Nonmetal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 12, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35647 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-26-M]

ANTHONY DALLY & SONS, INC.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 24148) of Anthony Dally & Sons, Inc. to modify the application of 30 CFR 57.19-7 to its Quarry No. 6, Stephens Jackson Quarry, Doney Slate Co., Pit and Mill, Diamond Slate Co., Quarry and Mill Mines located in Northampton County, Pa., in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-

164. MSHA has determined that the application of the standard to the mines will result in a diminution of safety to the miners of the mines.

MSHA based its determination on the following findings:

1. The petitioner has established that absence of overspeed and overtravel devices on the subject hoists would not result in a diminution of safety to the miners of the subject mine.

2. The sudden stop of the man-hoisting conveyance by a "dead-man" switch or other mechanical device could create an unnecessary hazard.

During the investigation it was learned from studies by various governmental agencies and by private corporations (all well knowledgeable in this type of hoist), that it would not be advisable to enforce the use of these mechanical devices on the subject hoists stipulated by the petitioner. A greater safety hazard or factor could be encountered if the mandatory safety standard 57.19-7 was enforced on this type of operation.

3. It is recommended that the modification be granted subject to the following conditions:

a. A stand-by hoistman is to be present at all times when man trips are made. The signature of the stand-by hoistman is to be in the hoist logbook along with the regular hoistman's signature.

b. A signalman (motioner) is to be present at all times during man trips, positioned to have visual capability throughout the trip, and to have communications with the hoistman at all times.

c. Quarry work area communications with the hoistman to be applicable at all times.

4. All the above recommendations are presently in effect and have been for the past four years. Granting of this modification to mandatory safety standard 57.19-7 is contingent with the continuation of these three conditions and subject to review and revocation annually.

Because of these findings, the Administrator for Metal and Nonmetal Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 13, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35648 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-20-M]

HOMESTAKE MINING CO.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted the petition (43 FR 24148) of Homestake Mining Company to modify the application of 30 CFR 57.9-112 to its Homestake Mine located in Lawrence County, South Dakota, in accordance with Section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164. MSHA has determined that an alternative method exists that will guarantee at all times no less than the same measure of protection given miners of the mine by the standard.

MSHA based its determination on the following findings:

1. The petitioner has established that trip lights are not feasible to install every time a train of two cars or less is moved by hand or by using a locomotive.

2. During MSHA's investigation it was established that safety would not be diminished if reflectors were used in place of trip lights under the following conditions:

a. Reflectors used in lieu of trip lights on supply trains not exceeding two supply cars in length and only when the supplies are low enough so as not to obstruct the motorman's forward vision of the area ahead of the trip.

b. Reflectors used in lieu of trip lights on cars or trains pushed by hand.

3. The petitioner has established that modification of the application of 30 CFR 57.9-112 would not lessen the degree of safety afforded miners hand tramping trains or when hauling two car trains where the motorman's forward vision is not obstructed by the train.

Because of these findings, the Administrator for Metal and Nonmetal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted as it pertains to hand pushed trains and two car or less trains, where the motorman's forward vision is not obstructed by the train.

A copy of the decision is available for inspection at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Virginia 22203.

Dated: December 8, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35649 Filed 12-21-78; 8:45 am]

[4510-43-M]

[Docket No. M-78-22-M]

PENN BIG BED SLATE CO., INC.

Final Action Granting a Petition for Modification of Application of Mandatory Safety Standard

The Mine Safety and Health Administration (MSHA) has granted in part the petition (43 FR 24149) of Penn Big Bed Slate Co., Inc., to modify application of 30 CFR 57.19-7 to its Manhattan Quarry Mine located in Lehigh County, Pa., in accordance with section 101(c) of the Federal Mine Safety and Health Act of 1977, Pub. L. 95-164. MSHA has determined that the application of the standard to the mine will result in a diminution of safety to the miners of the mine.

MSHA based its determination on the following findings:

1. The petitioner has established that absence of overspeed and overtravel devices on the subject hoists would not result in a diminution of safety to the miners of the subject mine.

2. The sudden stop of the man-hoisting conveyance by a "dead-man" switch or other mechanical device could create an unnecessary hazard.

During the investigation it was learned from studies by various governmental agencies and by private corporations (all well knowledgeable in this type of hoist), that it would not be advisable to enforce the use of these mechanical devices on the subject hoists stipulated by the petitioner. A greater safety hazard or factor could be encountered if the mandatory safety standard 57.19-7 was enforced on this type of operation.

3. It is recommended that the modification be granted subject to the following conditions:

a. A standby hoistman is to be present at all times when man trips are made. The signature of the standby hoistman is to be in the hoist logbook along with the regular hoistman's signature.

b. A signalman (motioner) is to be present at all times during man trips, positioned to have visual capability throughout the trip, and to have communications with the hoistman at all times.

c. Quarry work area communications with the hoistman to be applicable at all times.

4. All the above recommendations are presently in effect and have been for the past 4 years. Granting of this

modification to mandatory safety standard 57.19-7 is contingent with the continuation of these three conditions and subject to review and revocation annually.

Because of these findings, the Administrator for Metal and Nonmetal Mine Safety and Health, under authority delegated by the Secretary of Labor, ordered that the petition be granted.

A copy of the decision is available for inspection by the public at the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, 4015 Wilson Boulevard, Arlington, Va. 22203.

Dated: December 12, 1978.

ROBERT B. LAGATHER,
Assistant Secretary
for Mine Safety and Health.

[FR Doc. 78-35650 Filed 12-21-78; 8:45 am]

[4510-26-M]

Occupational Safety and Health Administration

[V-78-12]

GENERAL MOTORS CORP. AND CHRYSLER CORP.

Application for Variance and Grant of Interim Order; Correction

On page 53847 of the November 17, 1978 issue of the FEDERAL REGISTER (43 FR 53847) column 2, beginning on line two is the following sentence: "It also announces the granting of interim orders until a decision is rendered on the applications for variances."

As is explained in the Grant of Interim Order section of the notice, the interim orders were granted for a limited period of time, not until a decision is rendered on the applications. Column 3 of page 53849 states that the interim orders will remain in effect until January 8, 1979.

Therefore, the sentence in column 2, page 53847, beginning on line 2 is corrected to read, "It also announces the granting of interim orders until January 8, 1979."

In several other places in the notice reference is made to the fact that the applicants requested interim orders until a decision is made on the applications. These statements correctly reflect the applicants' requests.

Signed at Washington, D.C. this 15th day of December, 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

[FR Doc. 78-35646 Filed 12-21-78; 8:45 am]

[4510-28-M]

Office of the Secretary

[TA-W-4258]

ABERDEEN SPORTSWEAR CO., TRENTON, 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-4258: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on October 16, 1978 in response to a worker petition received on October 11, 1978 which was filed by the Amalgamated Clothing and Textile Workers Union on behalf of workers and former workers producing men's leather coats at Aberdeen Sportswear Company in Trenton, New Jersey.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50269). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Aberdeen Sportswear Company, 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.

Sales of men's leather coats, in both quantity and value, increased at Aberdeen Sportswear Company in 1977 compared with 1976 and continued to increase in the first three quarters of 1978 compared with the same period in 1977. Sales and production are equivalent at Aberdeen Sportswear Company.

CONCLUSION

After careful review, I determine that all workers of Aberdeen Sportswear Company, in Trenton, New Jersey 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 14th day of December 1978.

JAMES F. TAYLOR,
Director, Office of Management,
Administration, and Planning.

[FR Doc. 78-35651 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4142]

CASA LA GATA, INC., NEW YORK, 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-4142: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on September 13, 1978 in response to a worker petition received on September 8, 1978 which was filed on behalf of workers and former workers producing junior knit tops at Casa La Gata, Incorporated, New York, New York.

The Notice of Investigation was published in the FEDERAL REGISTER on September 26, 1978 (43 FR 43588). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Casa La Gata, 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. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses', and children's knit blouses and shirts decreased slightly from 24,366 thousand dozen in 1976 to 23,726 thousand dozen in 1977. During this same period the ratio of imports to domestic production also decreased from 81.8 percent in 1976 to 77.3 percent in 1977. In the first six months of 1978, however, imports of knit tops increased to 15,075 thousand dozen compared to 13,488 thousand dozen in the first six months of 1977.

The Department conducted a survey of some of the customers purchasing junior knit tops from Casa La Gata. Several of these customers indicated they reduced from Casa La Gata and increased purchases from foreign sources in the first six to nine months of 1978 compared to the same 1977 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 junior knit tops produced at Casa La Gata,

Incorporated, New York, New York, contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Casa La Gata, Incorporated, New York, New York, who become 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 13th day of December 1978.

JAMES F. TAYLOR,
Director, Office of Management,
Administration, and Planning.

[FR Doc. 78-35652 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4304]

CHAR-LEN HANDBAGS, INC., NEW HAVEN, CONN.

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-4304: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on October 30, 1978 in response to a worker petition received on October 26, 1978 which was filed on behalf of workers and former workers producing ladies' vinyl handbags at Char-Len Handbags, Incorporated, New Haven, Connecticut.

The Notice of Investigation was published in the FEDERAL REGISTER on November 7, 1978 (43 FR 51866). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Char-Len Handbags, 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. It is concluded that all of the requirements have been met.

U.S. imports of handbags increased both absolutely and relative to domestic production during 1977 compared to 1976. Imports of handbags increased absolutely during the first three quarters of 1978 compared with the first three quarters of 1977.

A survey of customers of handbags produced at Char-Len revealed that

surveyed customers have increased purchases of imported handbags while decreasing purchases from Char-Len.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' vinyl handbags produced at Char-Len Handbags, Incorporated, New Haven, Connecticut contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Char-Len Handbags, Incorporated, New Haven, Connecticut who became totally or partially separated from employment on or after October 24, 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 14th day of December, 1978.

JAMES F. TAYLOR,
Director, Office of Management,
Administration and Planning.

[FR Doc. 78-35653 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-3977]

CROSROL, INC., GREENVILLE, S.C.

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-3977: 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 19, 1978 in response to a worker petition received on July 13, 1978 which was filed on behalf of workers and former workers producing planetary collars at Crosrol, Inc., Greenville, South Carolina.

The Notice of Investigation was published in the FEDERAL REGISTER on July 28, 1978 (43 FR 32885). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Crosrol, 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.

Imports of planetary coilers declined both absolutely and relative to domestic production from 1976 to 1977, but increased both absolutely and relative to domestic production in the first six months of 1978 compared to the first six months of 1977.

The decline and finally the termination of coiler production at the Greenville plant was a direct result of the company's import activities. Crosrol's imports of finished coilers increased in quantity in the first seven months of 1978 compared to the same period of 1977. In April 1978, the company decided to stop producing coilers domestically and utilize imports as their entire source of planetary coilers for sale and distribution to customers.

None of the company's primary activities, including sales, distribution and installation of imported textile machinery, were affected by the discontinuation of domestic production of coilers.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with planetary coilers produced at the Greenville, South Carolina plant of Crosrol, Inc. contributed importantly to the decline in sales or 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 the Greenville, South Carolina plant of Crosrol, Inc. engaged in employment related to the production of planetary coilers who became totally or partially separated from employment on or after July 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 13th day of December 1978.

JAMES F. TAYLOR,
*Director, Office of
Management,
Administration, and Planning.*

[FR Doc. 78-35654 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4266]

DEFIANCE BLEACHERY CORP., BARROWSVILLE,
MASS.

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-4266: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on October 17, 1978 in response to a worker petition received on October 16, 1978 which was filed by the Defiance Relief Corporation on behalf of workers and former workers engaged in textile dyeing and finishing at Defiance Bleachery Corporation, Barrowsville, Massachusetts. The Notice of Investigation omitted reference to the union filing the petition.

The Notice of Investigation was published in the FEDERAL REGISTER on October 27, 1978 (43 FR 50271). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Defiance Bleachery Corporation, its customers, the National Cotton Council, the American Textile Manufacturers Institute, 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.

The ratio of imported finished fabric to domestically produced finished fabric increased from 1.8 percent in 1976 to 1.9 percent in 1977. Finished fabric imports increased absolutely from 187 million square yards in the first six months of 1977 to 255 million square yards in the first six months of 1978.

The Department conducted a survey of Defiance Bleachery Corporation's customers. The survey indicated that some customers increased purchases of imported fabric in the period 1976 through September 1978. During the same period, some of those customers who increased import purchases decreased purchases of fabric from Defiance Bleachery.

CONCLUSION

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with dyed and finished fabric produced at Defiance Bleachery Corporation contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

"All workers of Defiance Bleachery Corporation, Barrowsville, Massachusetts who became totally or partially separated from employment on or after March 25, 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 14th day of December, 1978.

HARRY J. GILMAN,
*Acting Director, Office of
Foreign Economic Research.*

[FR Doc. 78-35655 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-3866]

HEPPENSTALL CO., PITTSBURGH, 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-3866: 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 9, 1978 which was filed by the United Steelworkers of America on behalf of workers and former workers producing commercial steel forgings and die blocks at Heppenstall Company, Pittsburgh, Pennsylvania. The investigation revealed that die blocks are one type of forging and that materials handling devices were also produced.

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 determination was based upon information obtained principally from officials of Heppenstall Company, 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 materials handling devices, 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.

Evidence developed during the course of the investigation indicated that customers of the subject firm did not utilize foreign sources for the purchase of materials handling equipment. In a survey of Heppenstall Company's major domestic customers for such equipment, none of the customers reported any purchases of import-

ed materials handling equipment in 1976, 1977, and the first half of 1978.

With respect to workers producing steel forgings, all of the group eligibility requirements of Section 222 of the Act have been met.

Imports of steel forgings increased from 57.1 thousand short tons in 1976 to 82.1 thousand short tons in 1977. In the first six months of 1978, imports increased to 63.1 thousand short tons compared with 38.1 thousand short tons in the first six months of 1977. The ratio of imports to domestic production increased from 3.3 percent in 1976 to 4.2 percent in 1977.

A survey of Heppenstall Company's major domestic customers for steel forgings revealed that a major customer, whose decline in purchases of forgings from Heppenstall accounted for a significant percentage of the subject firm's decline in sales, increased purchases of imported forgings from 1976 to 1977 and in the first half of 1978 compared with the first half of 1977. Three other customers decreased purchases of forgings from Heppenstall in the first half of 1978 compared with the corresponding period in 1977, while increasing purchases of imported forgings.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with steel forgings produced at Heppenstall Company, Pittsburgh, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with provisions of the Act, I make the following certification:

"All workers of Heppenstall Company, Pittsburgh, Pennsylvania engaged in employment related to the production of steel forgings who became totally or partially separated from employment on or after May 15, 1977 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974."

I further determine that workers engaged in employment related to the production of materials handling devices at Heppenstall Company, Pittsburgh, Pennsylvania are denied eligibility to apply for adjustment assistance.

Signed at Washington, D.C. this 13th day of December 1978.

JAMES F. TAYLOR,
Director, Office of Management
Administration, and Planning.

[FR Doc. 78-35656 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4071]

INTERNATIONAL SILVER CO., FACTORY C, MERIDEN, CONN.

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-4071: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on August 17, 1978, in response to a worker petition received on August 16, 1978, which was filed by the United Steelworkers of America on behalf of workers and former workers producing stainless steel flatware, silver-plated fluted and silver-plated holloware at International Silver Co., Factory C, Meriden, Conn. The investigation revealed that Factory C produces only flatware.

In a determination signed on February 18, 1976, all workers at International Silver Co., Factory C, Meriden, Conn., engaged in employment related to the production of stainless steel flatware and engaged in employment related to the production of silver-plated flatware were certified as eligible to apply for adjustment assistance. The certification expired on February 18, 1978. (See TA-W-352).

The Notice of Investigation was published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39194). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of International Silver Co., The Sterling Silversmiths Guild, 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 stainless steel flatware, it is concluded that all of the requirements have been met.

Imports of stainless steel flatware increased from 1976 to 1977 and in the first 6 months of 1978 compared to the same period in 1977. The ratios of imports to domestic production and consumption have demonstrated an upward trend and have been at high levels throughout the 1973 through 1977 period. In 1977, the ratios of imports to domestic production and consumption were 304.3 percent and 75.4 percent, respectively. Three out of

every four pieces of stainless steel flatware sold in the United States in 1977 were imported. Currently there is no tariff quota on imports of stainless steel flatware.

Company imports of stainless steel flatware more than doubled, in terms of quantity, from 1976 to 1977. Imports, in quantity, in the first 6 months of 1978 were above the comparable 6 months period in 1976. Company imports of stainless steel flatware increased, in terms of value, from 1976 to 1977 and in the first 6 months of 1978 compared to the same period in 1977, while sales of domestically manufactured stainless steel flatware were declining.

With respect to workers producing silver-plated flatware, 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 silver-plated flatware increased in the first 9 months and in the first 8 months, respectively, of 1978 compared to the same period 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 stainless steel flatware produced at International Silver Co., Factory C, Meriden, Conn., contributed importantly to the decline in sales or 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 International Silver Co., Factory C, Meriden, Conn., engaged in employment related to the production of stainless steel flatware who became totally or partially separated from employment on or after February 18, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

I further determine that all workers of International Silver Co., Factory C, Meriden, Conn., engaged in employment related solely to the production of silver-plated flatware 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 13th day of December 1978.

JAMES F. TAYLOR,
Director, Office of Management,
Administration, and Planning.

[FR Doc. 78-35657 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4075]

MORRISON STEEL CO., NEW BRUNSWICK, 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-4075: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in section 222 of the Act.

The investigation was initiated on August 17, 1978 in response to a worker petition received on August 15, 1978 which was filed on behalf of workers and former workers cutting all types of steel to order from stock at the Morrison Steel Company, New Brunswick, New Jersey.

The Notice of Investigation was published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39194). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of the Morrison Steel Company 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 has determined that services are not "articles" within the meaning of section 222(3) of the Act.

The Department's investigation revealed that the Morrison Steel Company is an independent steel service center which processes and distributes steel. The company purchases coils from several steel manufacturers and then cuts and levels the steel according to customer specifications or ships the steel unaltered. The Morrison Steel Company is engaged solely in the processing and distribution of steel and does not produce an article within the meaning of section 222(3) of the Act.

CONCLUSION

After careful review, I determine that all workers of the Morrison Steel Company, New Brunswick, New Jersey 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 14th day of December 1978.

HARRY J. GILMAN,
Acting Director, Office of
Foreign Economic Research.

[FR Doc. 78-35658 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-4082]

REID-MEREDITH, INC., LAWRENCE, MASS.

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-4082: Investigation regarding certification of eligibility to apply for worker adjustment assistance as prescribed in Section 222 of the Act.

The investigation was initiated on August 18, 1978 in response to a worker petition received on August 18, 1978 which was filed on behalf of workers and former workers producing men's and women's hairpieces at Reid-Meredith, Incorporated, Lawrence, Massachusetts.

The Notice of Investigation was published in the FEDERAL REGISTER on September 1, 1978 (43 FR 39193). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Reid-Meredith, 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. It is concluded that all of the requirements have been met.

Imports of synthetic men's and women's hairpieces decreased in quantity from 14,866,463 pieces in 1976 to 11,698,209 pieces in 1977. The ratio of imports to domestic production decreased from 54,456.0 percent in 1976 to 49,359.5 percent in 1977. Imports increased from 8,025,200 pieces in the first 8 months of 1977 to 8,132,000 for the same period 1978. The imports to production ratio increased from 49,234.4 percent to 67,766.7 in terms of quantity.

The Department survey of customers of Reid-Meredith, Incorporated revealed some customers decreased purchases of hairpieces and wigs from the subject firm while they increased purchases of imports during 1977 and in the first eight months of 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 men's and women's hairpieces produced at Reid-Meredith, Incorporated, Lawrence, Massachusetts contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In

accordance with the provisions of the Act, I make the following certification:

"All workers of Reid-Meredith, Incorporated, Lawrence, Massachusetts who became totally or partially separated from employment on or after August 15, 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 14th day of December, 1978.

HARRY J. GILMAN,
Acting Director, Office of
Foreign Economic Research.

[FR Doc. 78-35659 Filed 12-21-78; 8:45 am]

[4510-28-M]

[TA-W-3994]

THOMAS MENSWEAR CORP., 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-3994: 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 25, 1978 in response to a worker petition received on July 18, 1978 which was filed on behalf of workers and former workers selling men's and boy's knit shirts at Thomas Menswear Corporation, New York, New York.

The Notice of Investigation was published in the FEDERAL REGISTER on August 1, 1978 (43 FR 33840). No public hearing was requested and none was held.

The determination was based upon information obtained principally from officials of Thomas Menswear Corporation 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 has determined that services are not "articles" within the meaning of Section 222(3) of the Act and that independent firms for which the subject firm provides services cannot be considered to be the "workers' firm."

Thomas Menswear Corporation was founded in New York, New York in 1971. Thomas Menswear Corporation functions as the exclusive sales agent for a manufacturer of men's and boys' knit shirts. In this capacity, Thomas Menswear maintains daily sales contact with the manufacturer's customers, provides design and styling concepts for the product line which is sold directly to retailers and wholesalers, and confers with the manufacturer's production department with respect to

the design of the product in accordance with customers' needs.

Thomas Menswear solicits orders for the manufacturer but all contracts are made with the manufacturer. All orders solicited by Thomas must be approved by the manufacturer as to terms and price.

Thomas Menswear has only one facility. That facility consists of a sales showroom and office space. Fifty percent of the equipment used is owned by Thomas; the balance of the equipment and all of the facilities are rented from the manufacturer.

Workers at Thomas Menswear are engaged in selling apparel and do not produce an article within the meaning of Section 222(3) of the Trade Act.

Thomas Menswear, the manufacturer for whom it acts as sales agent, and that manufacturer's customers have no controlling interest in each other.

All workers engaged in selling apparel at Thomas Menswear are employed by Thomas Menswear. All personnel actions and payroll transactions are controlled by Thomas Menswear. All employee benefits are provided and maintained by Thomas Menswear. Workers are not at any time under supervision or employment by customers of Thomas Menswear. Thus, Thomas Menswear must be considered the "workers' firm."

CONCLUSION

After careful review, I determine that all workers of Thomas Menswear Corporation, New York, New York 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 13th day of December 1978.

JAMES F. TAYLOR,

*Director, Office of Management,
Administration, and Planning.*

[FR Doc. 78-35660 Filed 12-21-78; 8:45 am]

[4510-23-M]

MINIMUM WAGE STUDY COMMISSION

MEETING

DECEMBER 19, 1978.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Commission meeting:

NAME: Minimum Wage Study Commission.

DATE: January 9, 1979.

PLACE: Room 550, 2000 K Street NW., Washington, D.C. Persons desiring to attend will be admitted to the extent seating is available.

TIME: 10:00 a.m.

Proposed Agenda:

- I. Wage Distribution Study
- II. Survey of Noncompliance
- III. Conglomerate Study
- IV. Priorities—Inflation and Youth.
- V. Organizational Matters—Staffing and Space
- VI. Pending Business

The reason for not publishing this notice within the 15-day period prior to the meeting is due to the need to acquire adequate space for the meeting. The next meeting of the Commission will be held Tuesday, February 13, 1979.

All communications regarding this Commission should be addressed to Mr. Louis E. McConnell, Executive Director, 1430 K Street NW., Suite 500, Washington, D.C. 20005. (202) 376-2450.

LOUIS E. MCCONNELL,
Executive Director.

[FR Doc. 78-35626 Filed 12-21-78; 8:45 am]

[7536-01-M]

NATIONAL FOUNDATION ON THE ARTS AND HUMANITIES

HUMANITIES PANEL

Meeting

DECEMBER 19, 1978.

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at 806 15th Street, N.W., Washington, D.C. 20506:

1. Date: January 9 and 10, 1979.

Time: 9 a.m. to 5:30 p.m.

Room: 807.

Purpose: To review NEH Pilot applications submitted to the National Endowment for the Humanities for projects beginning after April 1, 1979.

2. Date: January 11 and 12, 1979.

Time: 9 a.m. to 5:30 p.m.

Room: 1025.

Purpose: To review NEH Pilot applications submitted to the National Endowment for the Humanities for projects beginning after April 1, 1979.

3. Date: January 19, 1979.

Time: 9 a.m. to 5:30 p.m.

Room: 301.

Purpose: To review NEH Fellowships in Category B applications in Music submitted to the National Endowment for the Humanities for projects beginning after January 1, 1979.

Because the proposed meetings 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 meetings would fall within exemptions (4) and (6) of 5 U.S.C. 552b(c) and that it is essential to close these meetings 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, N.W., Washington, D.C. 20506, or call 202-724-0367.

STEPHEN J. MCCLEARY,
*Advisory Committee
Management Officer.*

[FR Doc. 78-35682 Filed 12-21-78; 8:45 am]

[7537-01-M-]

MUSEUM ADVISORY PANEL

Meeting

Pursuant to Section 10 (a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Museum Advisory Panel to the National Council on the Arts will be held January 16, 1979, from 9:00 a.m. to 5:30 p.m., and January 17, 1979 from 9:00 a.m. to 5:30 p.m., in room 1422, Columbia Plaza Office Building, 2401 E Street, NW, Washington, D.C.

A portion of this meeting will be open to the public on January 16, 1979, from 9:00 a.m. to 5:30 p.m. The topic of discussion will be Policy and Guidelines.

The remaining sessions of this meeting on January 17, 1979, from 9:00 a.m. to 5:30 p.m. are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the FEDERAL REGISTER March 17, 1977, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and (9)(b) of section 552(b) of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

JOHN H. CLARK,
*Director, Office of Council and
Panel Operations, National
Endowment for the Arts.*

[FR Doc. 78-35573 Filed 12-21-78; 8:45 am]

[7590-01-M]

NUCLEAR REGULATORY COMMISSION

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS, SUBCOMMITTEE ON EXTREME EXTERNAL PHENOMENA

Meeting

The ACRS Subcommittee on Extreme External Phenomena will hold an open meeting on January 9, 1979 at the Department of Energy Auditorium, 2753 South Hyland Drive, Las Vegas, Nev., 89102 to review NRC sponsored research regarding seismic design of nuclear power plants. Notice of this meeting was published October 20, November 20, 1978 (43 FR 49080, 54147, respectively).

In accordance with the procedures outlined in the FEDERAL REGISTER on October 4, 1978 (43 FR 45926), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far as in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The agenda for subject meeting shall be as follows:

Tuesday, January 9, 1979, 8:30 a.m. until the conclusion of business.

The Subcommittee may meet in Executive Session, with any of its consultants who may be present, to explore and exchange their preliminary opinions regarding matters which should be considered during the meeting and to formulate a report and recommendations to the full Committee.

At the conclusion of the Executive Session, the Subcommittee will hear presentations by and hold discussions with representatives of the NRC Staff, and their consultants, pertinent to the above topics. The Subcommittee may then caucus to determine whether the matters identified in the initial session have been adequately covered and whether the project is ready for review by the full Committee.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefore can be obtained by a prepaid telephone call to the Designated Federal Employee for this meeting, Dr. Richard P. Savio (telephone 202/634-

3267) between 8:15 a.m. and 5:00 p.m., EST.

Dated: December 18, 1978.

JOHN C. HOYLE,
Advisory Committee
Management Officer.

[FR Doc. 78-35560 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket Nos. 50-325 and 50-324]

BRUNSWICK STEAM ELECTRIC PLANT AND CAROLINA POWER & LIGHT CO.

Issuance of Amendments to Facility Operating Licenses and Negative Declaration

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 42 to Facility Operating License No. DPR-62 and Amendment No. 17 to DPR-71 issued to Carolina Power and Light Company, which revised the licenses for operation of the Brunswick Steam Electric Plant, Unit Nos. 1 and 2 located in Brunswick County, North Carolina. The amendments are effective as of the date of issuance.

The amendments delete the installation date of January 1, 1979 for cooling tower completion and require instead that the date be that established by the U.S. Environmental Protection Agency in its adjudicatory hearing proceeding on the facility's Section 402 Federal Water Pollution Control Act permit.

The application for the amendments complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Notice of Proposed Issuance of Amendment to Facility Operating Licenses in connection with this action was published in the FEDERAL REGISTER on November 10, 1977 (42 FR 58582). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Commission has prepared an environmental impact appraisal for the amended licenses and has concluded that an environmental impact statement for this particular action is not warranted because (1) It is appropriate to defer to decisions to be made by EPA as to the choice and installation date of the cooling system and (2) the results of this appraisal have not altered the fundamental conclusions of the FES.

For further details with respect to this action, see (1) the application for amendment dated March 4, 1977, (2) Amendment No. 42 to License No.

DPR-62, (3) Amendment No. 17 to License No. DPR-71, and (4) the Commission's Environmental Impact Appraisal. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. and at the Southport-Brunswick County Library, 109 W. Moore Street, Southport, North Carolina 28461. A copy of items (2), (3) and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Site Safety and Environmental Analysis.

Dated at Bethesda, Maryland this 15th day of December 1978.

For the Nuclear Regulatory Commission.

RONALD L. BALLARD,
Chief, Environmental Projects
Branch 1, Division of Site
Safety and Environmental
Analysis.

[FR Doc. 78-35564 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket Nos. STN 50-488, 50-489 and 50-490]

DUKE POWER CO. (PERKINS NUCLEAR STATION, UNITS 1, 2, AND 3)

Hearing

TAKE NOTICE that an evidentiary hearing in the above-captioned matter to consider alternate sites and generic safety matters will convene at 9:00 a.m., January 29, and continue through February 2, 1979, in Mocksville, North Carolina. On January 29, 1979, the hearing will be held in the Auditorium of the Davie County Office Building on South Main Street. On January 30 through February 2, the hearing will be held in the Courtroom of the Davie County Courthouse on South Main Street. Limited appearance statements will be heard Monday morning, January 29.

IT IS SO ORDERED.

Dated at Bethesda, Maryland this 15th day of December 1978.

FOR THE ATOMIC SAFETY AND LICENSING BOARD.

ELIZABETH S. BOWERS,
Chairman.

[FR Doc. 78-35561 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket No. 50-320]

METROPOLITAN EDISON CO. ET AL.**Issuance of Amendment to Facility Operating License**

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment 8 to Facility Operating License No. DPR-73, issued to the Metropolitan Edison Company, Jersey Central Power & Light Company, and Pennsylvania Electric Company, for operation of the Three Mile Island Nuclear Station, Unit 2 (the facility), located in Dauphin County, Pennsylvania. The amendment is effective as of its date of issuance.

The license is amended by revising certain Technical Specifications to permit operation at reduced power levels with reduced reactor coolant system flow.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

The Commission has determined that the granting of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with this action.

For further details with respect to this action, see (1) Amendment No. 8, to Facility Operating License No. DPR-73, and (2) the Commission's related safety evaluation supporting Amendment No. 8 to Facility Operating License No. DPR-73. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the State Library of Pennsylvania, Commonwealth and Walnut Streets, Harrisburg, Pennsylvania 17126.

Dated at Bethesda, Maryland, this 15th day of December 1978.

FOR THE NUCLEAR REGULATORY COMMISSION.

STEVEN A. VARGA,
Chief, Light Water Reactors
Branch 4, Division of Project
Management.

[FR Doc. 78-35563 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket Nos. 50-275 and 50-323]

PACIFIC GAS & ELECTRIC CO. (DIABLO CANYON NUCLEAR POWER PLANT, UNITS 1 AND 2)**Issuance of Amendment to Construction Permits**

The U.S. Nuclear Regulatory Commission (NRC) has issued Amendments 1 and 4, respectively, to Construction Permit Nos. CPPR-39 and CPPR-69 issued to the Pacific Gas and Electric Company for Diablo Canyon Nuclear Power Plant, Units 1 and 2, located in San Luis Obispo County, California.

The amendments provide for the addition of certain antitrust conditions. The Diablo Canyon Nuclear Power Plant is not subject to an antitrust review under Section 105C of the Atomic Energy Act, as amended. More recent nuclear power plants are subject to such review. However, in connection with the NRC's proceedings on the Stanislaus Nuclear Project, Pacific Gas and Electric Company agreed to include antitrust commitments as conditions in the Diablo Canyon licenses in certain circumstances which have occurred.

In a letter to the U.S. Department of Justice (DOJ), dated April 30, 1976, PG&E stated that, in the event a construction permit for the Stanislaus Nuclear Project was not issued by the NRC prior to July 1, 1978, PG&E was willing to have its license(s) for the Diablo Canyon Nuclear Power Plants, Units 1 and 2, amended to incorporate certain antitrust commitments. This willingness was contingent upon the DOJ advising the NRC that no antitrust hearing was necessary in connection with licensing the Stanislaus Project. The DOJ provided such advice in a letter dated May 5, 1976.

Since no construction permit for the Stanislaus Project had yet been issued, the NRC staff advised PG&E, in a letter dated September 15, 1978, of its intention to include the antitrust commitments as conditions in the Diablo Canyon Construction Permits. PG&E responded, in a letter dated September 19, 1978, stating that it had no objection to such an amendment.

The amendments comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations. The staff has made appropriate findings as required by the Act and the Commission's regulations in 10 CFR Chapter I, which are set forth in the amendment.

In accordance with 10 CFR 50.91, prior public notice of these amendments was not required since the amendments do not involve significant hazards considerations.

The staff has determined that the issuance of these amendments will not result in any significant environmental impact and that pursuant to 10 CFR Section 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of these amendments.

For further details with respect to this action, see (1) letters related to the amendments dated April 20, 1976, May 5, 1976, September 15, 1978, and September 19, 1978, (2) Amendment Nos. 1 and 4 to CPPR-39 and CPPR-69, respectively, and (3) the staff's related Evaluation of an Amendment to Include Antitrust Conditions in the Diablo Canyon Construction Permits.

All of these items and other related material are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Local Public Document Room located in San Luis Obispo County Free Library, P.O. Box X, San Luis Obispo, California 93406.

A copy of items (1), (2), and (3) may be obtained upon written request to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, ATTN: Director, Division of Project Management, Office of Nuclear Reactor Regulation.

Dated at Bethesda, Maryland, this 6th day of December 1978.

FOR THE NUCLEAR REGULATORY COMMISSION.

JOHN F. STOLZ,
Chief, Light Water Reactors
Branch No. 1, Division of Project
Management.

[FR Doc. 78-35565 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket No. 50-312]

SACRAMENTO MUNICIPAL UTILITY DISTRICT**Issuance of Amendment to Facility Operating License**

The U. S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 26 to Facility Operating License No. DPR-54, issued to Sacramento Municipal Utility District, which revised Technical Specifications for operation of the Rancho Seco Nuclear Generating Station (the facility) located in Sacramento County, California. The amendment is effective as of its date of issuance.

The amendment revises the Technical Specifications to reflect plant operating limits for the fuel loading to be used during Cycle 3.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act

of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement, or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) the application for amendment dated September 13, 1978, as supplemented November 15, 1978, (2) Amendment No. 26 to License No. DPR-54, (3) the Commission's related Safety Evaluation, and (4) the Exemption related to requirements of 10 CFR 50.46(a)(1). All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C., and at the Business and Municipal Department, Sacramento City-County Library, 828 I Street, Sacramento, Calif. A copy of items (2), (3), and (4) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Md., this 15th day of December 1978.

For the Nuclear Regulatory Commission.

GERALD B. ZWETZIG,
Acting Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 78-35562 Filed 12-21-78; 8:45 am]

[7590-01-M]

[Docket No. 40-8681]

ENERGY FUELS NUCLEAR, INC.

Availability of Draft Environmental Statement for White Mesa Uranium Project

Pursuant to the National Environmental Policy Act of 1969 and the United States Nuclear Regulatory Commission's regulations in 10 CFR Part 51, notice is hereby given that a Draft Environmental Statement prepared by the Commission's Office of Nuclear Material Safety and Safeguards related to the application for

operation of the proposed White Mesa Uranium Project located in San Juan County, Utah, is available for inspection by the public in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C. 20555. The Draft Statement is also being made available at the Utah State Clearinghouse, Utah Planning Coordinator, Office of the Governor, State Capitol Building, Salt Lake City, Utah 84114 and the Southeastern Utah Association of Governments, Post Office Box 686, 109 S. Carbon Avenue, Price, Utah 84501. Requests for copies of the Draft Environmental Statement (NUREG-0494) should be addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C., Attention: Director, Division of Technical Information and Document Control 20555.

The Applicant's Environmental Report, as supplemented, submitted by Energy Fuels Nuclear, Inc., is also available for public inspection at the above-designated locations. Notice of availability of the Applicant's Environmental Report was published in the FEDERAL REGISTER on June 12, 1978. (43 FR 25390).

Pursuant to 10 CFR Part 51, interested persons may submit comments on the Applicant's Environmental Report, as supplemented, and the Draft Environmental Statement for the Commission's consideration. Federal and State agencies are being provided with copies of the Applicant's Environmental Report and the Draft Environmental Statement (local agencies may obtain these documents upon request). Comments are due by February 5, 1979. Comments by Federal, State, and local officials, or other persons received by the Commission will be made available for public inspection at the Commission's Public Document Room in Washington, D.C.

Upon consideration of comments submitted with respect to the Draft Environmental Statement, the Commission's staff will prepare a Final Environmental Statement, the availability of which will be published in the FEDERAL REGISTER.

Comments on the Draft Environmental Statement from interested persons of the public should be addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Fuel Cycle and Material Safety.

Dated at Silver Spring, Maryland, this 7th day of December, 1978.

For the Nuclear Regulatory Commission.

ROSS A. SCARANO,
Section Leader, Uranium Mill Licensing Section, Fuel Processing & Fabrication Branch, Division of Fuel Cycle & Material Safety.

[FR Doc. 78-35422 Filed 12-21-78; 8:45 am]

[3190-01-M]

OFFICE OF THE SPECIAL REPRESENTATIVE FOR TRADE NEGOTIATIONS

(Doc. No. 301-16)

GREAT PLAINS WHEAT, INC. COMPLAINT

Petition and Hearing

On November 2, 1978, the Chairman of the Section 301 Committee received from Great Plains Wheat, Inc. a petition alleging discriminatory and unfair trade practices and policies by the European Community (EC). The complaint alleges that the EC engages in injurious actions through the unjustified use of export subsidies (restitutions) for wheat being sold to "third country" markets, that is, markets other than the EC in which United States wheat producers also have an export interest.

In accordance with the request of Great Plains made on November 27, 1978, the complaint is being instituted pursuant to section 301 of the Trade Act of 1974 (Pub. L. 93-618; 88 Stat. 1978). The text of the complaint is as follows:

GREAT PLAINS WHEAT INC.,
Washington, D.C., November 2, 1978.
CHAIRMAN; SECTION 301 COMMITTEE, Office of the Special Trade Representative, Room 725, 1800 C Street NW., Washington, D.C. 20056.

COMPLAINT FILED PURSUANT TO SECTION 301 OF THE TRADE ACT OF 1974

1. *Complainant:* This complaint is filed by Great Plains Wheat, Inc. (G.P.W.). For the record, Great Plains Wheat is a wheat market development and promotion organization supported by wheat producers through their state wheat commissions in Colorado, Kansas, Minnesota, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. In addition to the central office in Washington, D.C. and the two regional offices in Latin America, G.P.W. maintains regional offices for the promotion of all five classes of U.S. wheat in Europe, the Middle East, and Africa.

The principal objective of the organization is the development, maintenance and expansion of U.S. wheat exports. The wheat producing states represented by members of this organization by far account for the majority of U.S. wheat production. Traditionally U.S. wheat farmers depend upon the foreign market to take 60% of their crop. Therefore, there can be little doubt that G.P.W. has a great economic interest in ex-

porting wheat from the United States to foreign markets.

Because of this economic interest in U.S. wheat exports, Great Plains Wheat respectfully requests that the President, under the authority granted to him by section 301 (a) (3) of the Trade Act of 1974, "take all appropriate and feasible steps" to obtain the elimination of the European Community's (E.C.) export subsidy (restitution) on wheat being sold to so-called "third-country" markets. The E.C.'s use of this unfair trade practice to export wheat had the effect of substantially reducing the sales of competitive U.S. wheat exports in foreign markets.

Great Plains Wheat requests immediate and effective redress from and the elimination of, injurious actions by the E.C. in its unjustified use of export subsidies for wheat. In subsequent paragraphs and the accompanying written brief, it will be shown clearly that the E.C. has in the past and now continues to engage in unfair wheat export pricing practices, which have displaced U.S. wheat exports and depressed prices to U.S. farmers. In order to bring about a discontinuation of the E.C. wheat export subsidies, the U.S. government should immediately implement counteractive measures in retaliation for the trade disruption suffered by U.S. farmers.

G.P.W.'s further objective in requesting retaliatory action against the E.C. is to insure that world wheat trade be conducted on the basis of fair and effective competition. Such a competitive environment must exist in order for the economic benefits of expanded world wheat trade to accrue to the most efficient producers of wheat—U.S. wheat farmers.

2. *Description of foreign practice which is the subject of this complaint:* The practice which is the subject of this sales to third-country markets. Reference to this unfair trade practice is found in section 301(a)(3) of the Trade Act of 1974 (19 U.S.C. 2411).

3. *Identification of laws or regulations which are the subject of this complaint:* Within the European Community the basic outlines of a common system of farm support and protection are described in Title II of the Treaty of Rome. Further, regulations relating to the organization of prices and markets for cereals are contained in Council Regulations No. 120/67/EEC (*Official Journal* of the European Community No. 117, 6/19/67).

Export subsidies are made available to E.C. wheat exporters by the E.C. Commission in two ways: (1) Current export subsidies on wheat for specific regions are published periodically in the *Official Journal* of the European Community. (2) Wheat subsidies are also made available to regions or countries not, specifically designated, through the E.C. export tender system. Under this system, the E.C. Commission invites bids from private traders for export sales of a specified amount of the commodity. In their bids the traders, among other things, indicate the lowest level of subsidy they are willing to accept in exporting a stated amount of the commodity to certain specified countries or regions. The E.C. Commission generally targets the amount of wheat available for subsidy to specific destination countries or regions.

4. *Identification of foreign countries which are the subject of the complaint:* The above regulations are binding in their entirety and directly applicable to all members within the European Community. The export subsidy system is the same for the whole Community, but the amount may differ according to the destination of the wheat export. Since August, 1978 significant volumes of subsidized E.C. wheat exports have been sold to Egypt, Portugal, Morocco, and Brazil. In addition to these actual sales, the Community has made available large subsidies for wheat exports to Poland, the People's Republic of China, and Finland.

5. *Identification of the product which is the subject of this practice:* The products involved are E.C. bread wheats.

6. *Information showing how much subsidy has the effect of substantially reducing sales of competitive U.S. products in other foreign markets:*

(I) Volume of trade involved: Due to the E.C.'s aggressive wheat export subsidy practice its commercial wheat exports will increase by approximately 4.4 million metric tons this year relative to last year's volume.

(II) Quantification of the economic or other impacts on the complainant and on U.S. commerce in general:

(a) Loss of U.S. wheat export volume: An increase of E.C. wheat exports by 4.4 million metric tons (a volume of which 75% would be accounted for by the U.S.) as a result of the export subsidy will result in a 3.3 million metric ton displacement in U.S. commercial wheat exports this year.

(4.4 mmt x 75% = 3.3 mmt)
(b) Loss of revenue to U.S. wheat producers:

(i) Reduced U.S. wheat exports: Reduced exports of 3.3 million metric tons at a price of approximately \$130 per ton = \$429 million.

(3.3 mmt x \$130 per ton = \$429 million)
(ii) From reduced price on total U.S. wheat sales: Reduced export sales of 3.3 million metric tons will result in an approximate 10% reduction in marketings of U.S. wheat (\$130 per ton x 10% = \$13 per ton). Total off-farm marketings are anticipated at 50 million tons = \$650 million.

(\$13 per ton x 50 million tons = \$650 million)

(iii) Total loss of revenue = \$1,079 million.

(c) Loss of export earnings to U.S. economy:

(i) From reduced U.S. wheat exports: Reduced exports of 3.3 million tons at \$150 per ton, a price that would have existed had it not been for the price-depressing effects of the E.C.'s wheat export subsidy = \$495 million.

(3.3 mmt x \$150 per ton = \$495 million)

(ii) From reduced prices on other U.S. wheat exports: Reduced prices of \$13 per ton times a total of U.S. wheat exports projected at 30 million metric tons = \$390 million.

(iii) Total loss of export earnings = \$885 million.

(III) International obligation and U.S. statute violated by this practice: The export subsidies paid by the E.C. to its wheat exporters violate Article XVI of the General Agreement on Tariffs and Trade (GATT). These export subsidies also fall within the U.S. Trade Act of 1974 (Public Law 93-618, Title III, Relief from Unfair Trade Practices, Chapter One, section 301(a)(3)).

7. *Filing for other forms of relief:* At present, Great Plains Wheat, Inc., has not filed

for any other forms of relief under the Trade Act of 1974 or any other act, believing that the President has sufficient authority under section 301 to cause the European Community to terminate its subsidy on wheat exports to foreign markets.

Great Plains Wheat as the complainant is concurrently requesting a public hearing under section 301(d)(2) of the Trade Act. A written brief has also been submitted in twenty copies. In order that the position of the complainant and the evidence be clear the complaint and written brief must be considered together.

Respectfully submitted,

MICHAEL L. HALL,
President, Great Plains Wheat, Inc.,
1030-15th Street, N.W., Suite 420,
Washington, D.C. 20005, telephone:
(202) 659-1240.

GREAT PLAINS WHEAT INC.,
Washington, D.C., November 2, 1978.
CHAIRMAN, SECTION 301 COMMITTEE, Office of
the Special Trade Representative, 1800
G Street NW., Washington, D.C. 20056.

REQUEST BY COMPLAINANT FOR A PUBLIC
HEARING UNDER SECTION 301(d)(2) OF THE
TRADE ACT OF 1974

Great Plains Wheat (G.P.W.) as the complainant request that a public hearing be held pursuant to Section 301(d)(2) of the Trade Act of 1974. This request for a public hearing is submitted concurrently with G.P.W.'s filing of a 301 complaint against the European Community's use of export subsidies on wheat sales to third-country markets. Also accompanying this request are twenty copies of a written brief.

Great Plains Wheat believes that it is in the public interest to hold such hearings and wishes to have the opportunity to present oral testimony when such hearings are held.

Respectfully submitted,

MICHAEL L. HALL,
President, Great Plains Wheat, Inc.,
1030-15th Street, N.W., Suite 420,
Washington, D.C. 20005, telephone:
(202) 659-1240.

GREAT PLAINS WHEAT INC.,
Washington, D.C., November 2, 1978.
CHAIRMAN, SECTION 301 COMMITTEE, Office of
the Special Trade Representative, 1800
G Street NW., Washington, D.C. 20056.

WRITTEN BRIEF SUBMITTED CONCURRENTLY
WITH COMPLAINT FILED PURSUANT TO SECTION
301 OF THE TRADE ACT OF 1974 (CFR
15.2006.6)

Great Plains Wheat respectfully requests that the President, under the authority granted to him by Section 301 (a) (3) of the Trade Act of 1974, "take all appropriate and feasible steps" to obtain the elimination of the European Community's (E.C.) export subsidy (restitution) on wheat being sold to so-called "third-country" markets. The E.C.'s use of this unfair trade practice has had the effect of substantially reducing the sales of competitive U.S. wheat exports in those foreign markets.

For the record, Great Plains Wheat, Inc., is a wheat market development and promotion organization supported by wheat producers through their state wheat commissions in Colorado, Kansas, Minnesota, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, and Wyoming. In addition to

the central office in Washington, D.C. and the two regional offices in Latin America, Great Plains Wheat (G.P.W.) maintains regional offices for the promotion of all five classes of U.S. wheat in Europe, the Middle East and Africa.

The principal objective of the organization is the development, maintenance and expansion of U.S. wheat exports. Wheat producing states represented by members of G.P.W. account for the majority of U.S. wheat production. Traditionally U.S. wheat farmers depend upon the foreign market to take 60% of their crop. Therefore, there can be little doubt that G.P.W. has a great economic interest in achieving an end to this unfair trade practice by the E.C.

Great Plains Wheat requests immediate and effective redress from, and elimination of, injurious actions by the European Community in its unjustified use of export subsidies for wheat. In both the complaint and this brief, it will be shown clearly that the E.C. has in the past and now continues to engage in unfair wheat export pricing practices, which have displaced U.S. wheat exports and depressed prices to U.S. farmers. In order to bring about a discontinuation of the E.C. wheat export subsidies, the U.S. government should immediately implement counteractive measures in retaliation for the trade disruption suffered by U.S. farmers.

G.P.W.'s further objective in requesting retaliatory action against the E.C. is to insure that world wheat trade be conducted on the basis of fair and effective competition. Such a competitive environment must exist in order for the economic benefits of expanded world wheat trade to accrue to the most efficient producers of wheat—U.S. wheat farmers.

Retaliatory and/or unilateral action may not be the best answer. However, such action is necessary if the E.C. does not cease immediately the use of wheat export subsidies. In addition to redress for U.S. wheat farmers, the President should also consider requesting a GATT panel to examine the E.C. wheat export subsidy practice as a substantial violation of Article XVI of the GATT that serves to distort and displace U.S. wheat trade patterns.*

U.S. DEPENDENCE ON WHEAT EXPORT MARKETS

U.S. wheat farmers are heavily dependent upon the world marketplace and cannot tolerate the burden of E.C. export subsidies. As the following table reflects, U.S. farmers depend on the export of almost 60% of their annual wheat production.

TABLE 1—U.S. Wheat Production and Exports

Year beginning June	Production in million bushels	Exports in million bushels	Exports as a percentage of production
1972/73.....	1,545	1,131	73.2
1973/74.....	1,705	1,217	71.4
1974/75.....	1,796	1,018	56.7
1975/76.....	2,135	1,173	54.9
1976/77.....	2,147	950	44.2
1977/78 ¹	2,026	1,100	54.3
1978/79 ²	1,920	1,000	52.1

*Australia has initiated a similar action in the GATT with respect to the E.C. practice of export subsidies on sugar, an action endorsed and supported by the United States in favor of Australia.

¹ Preliminary.
² Projected.

Source: National Association of Wheat Growers, *Wheat Facts*

U.S. agricultural exports, especially wheat and grains, are one of the few bright spots for our nation's economy. If it were not for the efficient U.S. agricultural production, our balance of trade position would be even more disastrous than is currently the situation. During the last several years U.S. agricultural exports have averaged approximately \$24 billion, allowing for a net agricultural trade surplus of \$10-12 billion annually. Had it not been for these vigorous export sales of U.S. agricultural products including wheat, our trade deficit would have been greater; we would not have been able to partially offset our huge oil import bill; and the dollar would have declined to even lower levels against the major foreign currencies than the current post-World War II record lows.

CURRENT E.C. SUPPLY SITUATION

U.S. wheat farmers are prepared and indeed eager to compete for the sales of wheat to all foreign markets; however, it is essential that such trade be conducted on the basis of fair and effective competition. Competitive trade is not possible when the E.C. uses export subsidies (restitutions). There are several fundamental reasons why the E.C. has had to resort again and in a blatant fashion to the use of wheat export subsidies (See Appendix A for comparative data on the U.S. and E.C. production and support price systems for wheat).

This year, because E.C. wheat production was artificially encouraged by very high support prices, the Community is expected to harvest a much larger than average crop of lower quality wheat. E.C. wheat farmers, in order to obtain a greater quantity of wheat eligible for these high supports, diverted their production to higher yielding, but lower quality wheat. As a result, E.C. domestic wheat production has increased from 38.5 mmt* last year to 47.0 mmt this year. It must be noted, however, that E.C. domestic wheat prices still remain above world prices.

Over the past several years, the E.C. year-end stocks were easily held at around 7 mmt because of smaller wheat crops. Given the current E.C. surplus situation, however, the Community has resorted to export subsidies in order to maintain this 7 mmt year-end level. In other words, the E.C. is exporting its problems at the expense of the more efficient world wheat producers.

This increase in European Community production comes at a time when U.S. farmers took positive actions to bring the world supply and demand for wheat into more proper alignment. U.S. wheat production this year will equal approximately 48.7 mmt as compared with 55.1 mmt last year.

Due to the Community's aggressive export subsidy practice, its wheat exports this year will increase from 5.5 mmt last year to an estimated 9.0 mmt this year. This represents an increase from 7% to 12% of world wheat exports, while the U.S. level and percentage of world wheat trade will remain basically unchanged. Without E.C. export subsidies, the U.S. would surely enjoy even greater wheat export volume in the various foreign markets to which the E.C. is exporting its surplus wheat production.

*Million metric tons.

The majority of world wheat import markets are primarily "price markets." Wheat offers are considered and accepted on the basis of the lowest bid with only secondary concern about quality factors. Through the use of export subsidies, the E.C. has been able to sell wheat which would otherwise not have been competitive with U.S., Canadian, or Argentine wheat.

E.C.'S CURRENT EXPORT SUBSIDY ACTIVITY

Since August of this year, marking the near completion of the European harvest, European wheat—essentially French milling wheat—or wheat flour has been sold with the assistance of substantial export subsidies (restitutions) to the following markets:

TABLE 2

Country	Quantity (mt)
Egypt.....	300,000
Portugal.....	60,000
Morocco.....	165,000
Brazil.....	90,000

In addition to the actual sales of European wheat to those markets with export subsidies in the range of U.S. \$105.00 to U.S. \$115.00 per metric ton, the E.C. Commission has made available the following quantities to the following markets:

TABLE 3

Country	Quantity (mt)
Poland.....	800,000
People's Republic of China.....	300,000
Finland.....	30,000

The following table shows that the E.C. Commission has, since August, authorized the subsidization of substantially larger quantities of wheat than were authorized in the same period over the last three years:

TABLE 4

Year	Volume (mt)	Subsidy range per (mt)
1978.....	1,507,000	U.S. \$103.00-\$115.00
1977.....	268,000	U.S. \$40.00-\$45.00
1976.....	224,000	U.S. \$40.00-\$45.00
1975.....	504,000	U.S. \$45.00-\$50.00

Out of 1.5 mmt authorized since August, the European Community Commission has approved the following subsidy levels:

TABLE 5

Date	Quantity (mt)	Actual subsidy per (mt)
September 7.....	153,000	U.S. \$103.07
September 14.....	195,000	U.S. \$104.17
September 21.....	315,000	U.S. \$104.17
September 28.....	232,000	U.S. \$103.62
October 26.....	21,000	U.S. \$115.98

Because only 916,000 mt of the eligible 1.5 mmt have been awarded a price level for the

subsidy through the tender system, one can realistically expect a further award of 583,000 mt within the immediate future. Subsequent subsidy levels allowed by the E.C. Commission through either the official published level in the *Official Journal* or the subsidy tender system will in fact be higher than the current levels because of two factors: (1) firmer world wheat prices, and (2) the record lows to which the U.S. dollar is being traded against the currencies of the European Community member countries.

Moreover, the commitment of the total 1.5 mmt of subsidy tenders will not exhaust the E.C. Commission's prerogative of authorizing additional quantities of wheat to be tendered at whatever price level required to make European wheat competitive in international markets.

It must be emphasized and well appreciated that it is impossible to make comparisons of E.C. wheat exports to most of the aforementioned countries because there is little recent history of any significant volume of European wheat exports to those foreign markets.

Not since the 1960s has the European Community exported wheat to the People's Republic of China with the assistance of an export subsidy. In recent years, E.C. wheat was only exported to Brazil in the 1974-75 season, and that quantity was relatively small—20,000 mt. Notwithstanding a bilateral grain agreement providing for up to 600,000 mt annually of either wheat or barley exports from France to Poland, insignificant quantities of E.C. wheat have been exported to Poland in recent years. This year the E.C. has authorized wheat export subsidies to move up to 800,000 mt to the Polish market which traditionally takes 2 mmt annually from all sources. The United States has been the predominant supplier of wheat to Poland, with France only a minor supplier of barley.

With respect to Morocco, Egypt, and Portugal, the United States is also the traditional and predominant supplier. At this early stage in the E.C. marketing season, the level of E.C. subsidies authorized for the quantities of wheat to these markets clearly shows that the European Community will substantially disrupt and displace U.S. wheat exports to these important foreign markets.

In order to better understand how this subsidy system works, we have included in Appendix B of this brief, a comprehensive description of the E.C.'s Common Agricultural Policy (CAP) for Grains.

OFFICIAL U.S. POSITION ON SUBSIDIES AND G.P.W. RECOMMENDATION

In requesting the President to "take all appropriate and feasible steps" to eliminate the European Community's export subsidy on wheat, Great Plains Wheat is not acting out of any protectionist motivation. In fact, it is G.P.W.'s conviction that such unfair trade practices are limiting the potential for expanded U.S. wheat trade.

Great Plains Wheat's request, then, is consistent with President Carter's message of September 26, 1978, on the urgent need to expand U.S. industrial and agricultural exports. The President stated:

[The] United States export performance is also adversely affected by the excessive financial credits and subsidies which some of our trading partners offer to their own exporters. One of our major objectives in the

MTN is to negotiate an international code restricting the use of government subsidies for exports.

Also in this regard, President Carter focused on the injurious practices of subsidizing exports. To Great Plains Wheat, the following statement by the President suggests an indirect reference to the overall European Community's practice of subsidizing exports not only to the United States but to third-country markets as well.

I hope that our major trading partners will see the importance of reaching more widespread agreements on the use of export finance, to avoid a costly competition which is economically unsound and ultimately self-defeating for all of us. These international agreements are essential to assure that American exporters do not face unfair competition and this Administration intends to work vigorously to secure them.

As a part of the Administration's "vigorous attempt" to secure a multilateral trade agreement which includes a meaningful subsidy code, President Carter has assured the European Community that Congress, when it reconvenes, will extend the countervailing duty waiver. The E.C. has threatened to break off the current trade talks unless this waiver is granted. In this regard, Great Plains Wheat recommends that the President tie the U.S. countervailing duty waiver extension to the E.C. cessation of wheat export subsidies while an overall trade agreement and a subsidy code are being finalized. Just as the European Community has claimed that they cannot negotiate with the treat of duties, the U.S. should not be expected to negotiate while its wheat trade is being disrupted and distorted by the European Community's use of export subsidies.

In conclusion, Great Plains Wheat strongly believes that the United States cannot sit

APPENDIX A—Wheat: Comparative Data on Supply-Disappearance; Support Prices and Export Subsidies for Marketing Years 1972-79

Marketing year	Production (m/mt)		Exports (m/mt)		Carryout (m/mt)		Support Price (U.S. \$/bu.)
	Volume	Percent	Volume	Percent	Volume	Percent	
1972-73							
U.S.	42.0	12	30.8	44	16.2	27	*0
E.C.	41.5	12	6.0	8	5.8	9	^b \$3.56
World	343.4	100	70.8	100	61.1	100	
1973-74							
U.S.	46.6	13	33.1	46	9.3	13	*0
E.C.	41.4	11	5.2	7	7.3	10	^b \$3.60
World	372.2	100	72.6	100	70.3	100	
1974-75							
U.S.	48.5	14	28.0	41	11.8	19	*\$2.05
E.C.	45.4	13	6.8	10	9.7	15	^b \$4.15
World	357.1	100	68.1	100	63.6	100	
1975-76							
U.S.	57.8	17	31.5	43	18.1	29	*\$2.05
E.C.	38.1	11	8.4	11	7.5	12	^b \$4.35
World	350.0	100	73.7	100	61.4	100	
1976-77							
U.S.	58.3	14	25.7	37	30.3	31	*\$2.29
E.C.	39.1	9	5.3	8	7.0	7	^b \$4.85
World	415.1	100	69.9	100	96.6	100	
1977-78							
U.S.	55.1	14	31.0	41	32.0	40	*\$2.47
E.C.	38.5	10	5.5	7	7.0	9	^b \$5.06
World	381.4	100	75.1	100	80.5	100	
1978-79*							
U.S.	48.7	12	31.0	41	29.1	36	*\$3.40
E.C.	47.0	11	9.0	12	7.0	9	^b \$5.63
World	412.4	100	74.9	100	80.1	100	

* U.S. target price

^b E.C. threshold price

* USDA/FAS projections

Source: USDA/FAS Foreign Agriculture Circular: Grains.

idly by and watch while important foreign markets for U.S. wheat exports are being lost to European wheat sales as a result of unfair trade practices. Every U.S. wheat sale lost because of a subsidized European sale has a direct impact not only on the U.S. wheat farmer, but also on the entire nation which so desperately needs increased exports to improve the U.S. balance of trade deficit.

The European Community in its use of wheat export subsidies is exporting its own problems at the expense of the U.S. and other efficient wheat exporters. One troublesome aspect of export subsidies is the tendency for one subsidy to invite counter-subsidies by other nations so as to protect their own export markets. Great Plains Wheat is supportive of official U.S. efforts to obtain a meaningful subsidy code in the current Multilateral Trade Negotiations that would eliminate the practice of export subsidies. G.P.W. is also supportive and serves as an advisor to the current efforts to renegotiate the International Wheat Agreement.

However, in Great Plains Wheat's judgment, no immediate relief can be expected through the traditional GATT procedures or from measures now likely to be formulated in the current Multilateral Trade Negotiations. Section 301 of the Trade Act offers the only immediate means for the U.S. to retaliate against the European Community's wheat export subsidies.

This written brief and the accompanying complaint clearly demonstrate that U.S. farmers are dependent upon their wheat export sales and that U.S. wheat sales are being lost as a result of the European Community's export subsidies. Therefore, it is imperative that the President act now, using the powers granted to him by Section 301.

APPENDIX B

The E.C.'s Common Agricultural Policy as it Relates to Wheat

In order to understand the nature of the E.C. export subsidies, it is important to review the basic agricultural policies of the Community.

The European Economic Community was created by the Treaty of Rome on March 27, 1957. The E.C., originally composed of six member countries, now unites the economies of nine nations: Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, and the United Kingdom. By the early 1980s, the European Community could well be expanded to twelve members including Spain, Portugal, and Greece.

The Common Agricultural Policy (CAP) forms a fundamental part of the European Community. The basic outline of this common system of farm support and protection was described in Title II of the Treaty of Rome.

Almost all significant agricultural products are now covered by a common market organization—that is, a CAP. However, the European Community's CAP for grains provides the best example of the operation of a common market organization in the agricultural sector. The regulations covering a unified market for grains in the E.C. came into effect on July 1, 1967.

The prices for the most important grains—including wheat—are supported by government purchasing of any amount offered at a fixed support or at "intervention prices." The intervention price is somewhat below the "target" price, which may be described as the desired wholesale price. The threshold price is equal to the target price, which is set for the most deficit grain area at Duisburg, Germany, minus transport costs from Rotterdam.

Imports are prevented from selling at less than the target price because their prices must meet the minimum report or "threshold" price. To insure that grains do not enter below the threshold price, the Community calculates each day a variable levy equal to the difference between the threshold price and the lowest CIF offer price for grain, adjusted for quality. This levy is added to the CIF price; the current variable import levy on wheat is approximately U.S. \$130 per metric ton.

The net effect of collecting this variable import duty at the border is to use such revenues to defray in large part the currently onerous levels of export subsidies for European wheat. Consequently U.S. wheat farmers face the unpalatable situation of having the E.C. Commission impose variable import levies on E.C. imports of higher quality U.S. wheat. In turn, the funds generated from

the variable import levy are then used to subsidize exports of lower quality E.C. wheat into traditional U.S. export markets. Simply stated, these variable import levies are set at whatever levels necessary to protect E.C. domestic wheat from lower priced imports and to cover the subsidies needed to lower E.C. wheat export prices.

Since E.C. support prices are set at exceedingly high levels and are protected from competition by means of the variable import levy, the export subsidy becomes essential in order to remove surplus production. These so-called export refunds or restitutions (subsidies) make it possible for grain to be exported from the Community to third countries when world prices are below E.C. prices, which is the traditional pricing pattern for E.C. wheat vis-a-vis U.S. and other major suppliers.

The matter of explaining E.C. restitution and reporting of such is not a simple matter. There are actually two levels of subsidies depending upon the area of the world considered. One is a subsidy level published in the E.C. *Official Journal* which could change every week. No level change occurs unless there are unusually large fluctuations in the world grain market price level or sharp fluctuations in exchange rates of major currencies. More importantly, the second subsidy level is set by weekly tenders by exporters within the E.C. Under this system, the E.C. Commission invites bids from private traders for export sales of a specified amount of the commodity.

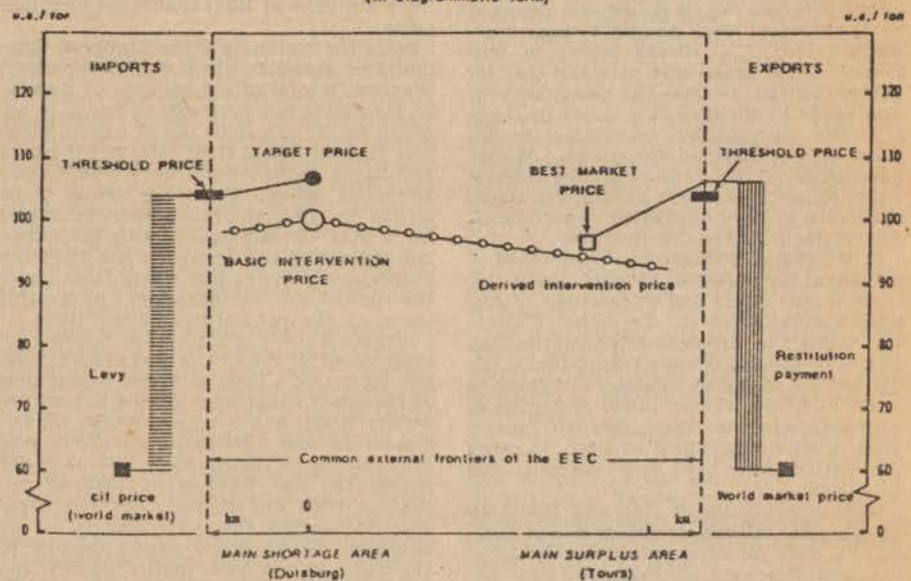
In their bids, traders, among other things, indicate the lowest level of subsidy they are

willing to accept in exporting a stated amount of the commodity to certain specified countries or regions. The size of the export subsidy is usually in line with the level of the import levy. Its purpose is to bridge the gap between the internal E.C. grain price and the external world price, thus allowing E.C. grain to compete with that from other sources. The amount of subsidy is generally targeted for specific destination countries or regions.

The E.C.'s target, intervention, and threshold prices as well as subsidies are established in a specially created standard of value called a unit of account (u.a.). The European Community's u.a. is the legal—but physically nonexistent—currency for agricultural products. The u.a. can be expressed in terms of U.S. dollars; the current conversion rate is U.S. \$1.00 = 1.64 u.a., which is adjusted daily because of the sharp fluctuations in the dollar value vis-a-vis the major European currencies.

Although "common" agricultural prices are fixed in terms of the units of account of the Community as a whole, farm prices vary widely among the various member states. To avoid "disruption" of the national markets because of these inevitable price differences, the E.C. has established a system of "monetary compensatory amounts" (MCA). These MCAs can be applied as either export subsidies/taxes or import subsidies/taxes on both intra-Community and third-country farm trade. It is therefore possible for export subsidies to vary slightly among the members.

PRICE SYSTEM APPLICABLE FOR WHEAT
(in diagrammatic form)



SOURCE: OECD Agricultural Policy Reports, *Agricultural Policy of the European Economic Community*.

GREAT PLAINS WHEAT INC.,

Washington, D.C., December 18, 1978.

Ambassador ROBERT S. STRAUSS,
Special Representative for Trade Negotiations,
1800 G Street, NW., Washington,
D.C. 20506.

DEAR MR. AMBASSADOR: I appreciate having the opportunity of meeting with you last Thursday, December 7, 1978, to review the data, merits and purpose of our complaint under Section 301 of the U.S. Trade Act of 1974 about the trade disruptive practices of the European Communities' use of export subsidies for making wheat sales to third-country markets. Subsequent to our meeting, I have commented in several public presentations on your commitment to give serious attention to our complaint and your firm conviction about protecting the international trade interest of U.S. wheat farmers in the current international trade negotiations.

Your representations about the use of wheat export subsidies have produced a degree of temporary responsibility on the part of the European Communities but temporary responsibility only in the case with Brazil. Nevertheless, all indications would suggest that the European Communities will resume the wheat export expansion program to Brazil solely on the basis of providing wheat export subsidies sometime early in 1979. In response to the official European Communities' statement that a special wheat export subsidy arrangement would be established for Central and South America, Mr. Henri Guitton, the President of the Brazilian Wheat Board, was reported by the Reuters News Agency to have commented that "... Brazil wants to buy French wheat again next year and that he [Henri Guitton] believes the tender suspension would be lifted soon, possibly in January." One can genuinely understand the position of the Brazilian Government Wheat purchasing official because of any buyer's desire to purchase wheat at such extraordinarily low prices provided by export subsidies by the European Communities.

In accordance with our mutual interest, I am taking the liberty of advising you of the latest export offers and transactions of European wheat since our December 7 meeting. While the European Communities may in fact be somewhat more responsible in the blatant use of export subsidies for wheat as grain in Brazil, export offers and sales of European wheat as grain, and particularly sales of European wheat as flour, to other destinations have been very aggressive and significant.

Sizable quantities of U.S. and European wheats were offered for export sale to Tunisia this week for shipment during the January and February shipping position. Because of the sustained use of EEC wheat export subsidies, the European wheat was offered at prices reported at US\$126.00 per metric ton (or US\$3.43 per bushel) landed at Tunisian ports compared to prices reported at US\$1236.00 per metric ton (or US\$3.70

per bushel) FOB Gulf ports. It is almost impossible to calculate the EEC wheat export subsidies on these offers because U.S. wheats were offered on an FOB basis and the French wheats on a c & f basis. Nevertheless, the landed cost of U.S. wheat in Tunisia would be in the neighborhood of US\$147.00 per metric ton (or approximately US\$4.00 per bushel), which would suggest an EEC wheat export subsidy in the neighborhood of about US\$130.00 per metric ton (or US\$3.54 per bushel) in order to make European wheat US\$11.00 per metric ton (or US\$0.30 per bushel) cheaper than U.S. wheat. Both the U.S. and European wheat export offers were rejected in favor of the accepted wheat export offers of 40,000 tons of wheat from Turkey at prices as low as US\$125.00 per metric ton (or US\$3.40 per bushel) FOB Turkish ports.

European wheat flour is again being sold to Sri Lanka with the assistance of an excessive export subsidy. During the week, a total of 120,000 tons of wheat (or 2,645,000 hundredweights) were sold at a reported landed price of US\$194.44 c & f at ports in Sri Lanka. In my letter of November 27, 1978, to you, I reported that the EEC wheat export subsidy would have to be around US\$185.00 per metric ton (or an equivalent of US\$5.65 per bushel) for such wheat flour export sales to Sri Lanka. There is no reason to believe that the EEC wheat export subsidy level has been reduced, allowing for a total of 180,000 tons of European flour to be sold to that country with the assistance of export subsidies. A further export sale of 150,000 tons of European flour was reportedly sold to Egypt this week, and at an unconfirmed but astoundingly low price of US\$142.50 c & f Egyptian ports.

Since the beginning of the European Communities' aggressive wheat export expansion program, a total of 450,000 tons of European flour have now been sold to Egypt. In addition to the egregious use of export subsidies to make wheat flour sales to Sri Lanka and Egypt, these sales of heavily subsidized European wheat flour are being made during the final stages of the negotiations for a P.L. 480 Agreement with Sri Lanka and increasing the resolve of the Egyptian authorities to reject U.S. wheat flour under the current P.L. 480 Agreement in favor of the much cheaper European wheat flour.

Although there is a reported "temporary suspension" of the EEC wheat export subsidies to Brazil, a total of 67,500 metric tons of European wheat were offered against the weekly Brazil wheat import tender on December 13. And, although these offers were prices as low as US\$130.95 to US\$133.99 per metric ton (or US\$3.56 to US\$3.65 per bushel) FOB French ports for February/March shipment, they were rejected by the Brazilian Wheat Board simply because of the need to purchase higher quality and protein in U.S. Hard Red Winter wheats. The Brazilian Wheat Board purchased 104,000 tons of U.S. wheat at US\$137.11 to US\$138.11 per metric ton (or US\$3.73 to US\$3.76 per bushel) FOB Gulf ports for shipment during February to April. Nevertheless,

a total of 67,500 tons of European wheat were offered at the Brazilian tender this week, and at prices in a range of US\$130.95 to US\$133.99 per metric ton (or US\$3.56 to US\$3.65 per bushel) FOB French ports for the same shipping months. Consequently, the heavily subsidized European wheats are still being offered to Brazil—and at prices between US\$4.12 to US\$6.16 per metric ton (or US\$0.11 to US\$0.17 per bushel) lower than U.S. wheat export offers. And consequently, the EEC wheat export subsidy still remains at US\$120.00 per metric ton (or US\$3.27 per bushel) in order for French European wheats to be offered at such a discount to U.S. wheat calculated on an FOB basis between French ports and Gulf ports.

A further disturbing feature of the aggressive wheat export expansion program of the European Communities is the reaction from other major wheat producing and exporting countries. This concern is best illustrated by the offers of Argentine wheat this week at the Brazilian Wheat Board tender, all of which were rejected. A total of about 275,000 tons of Argentine wheat were offered for shipment during the February-April period—and at prices as low as US\$127.73 to US\$133.50 per metric ton (or US\$3.48 to US\$3.63 per bushel) FOB Argentine ports. These Argentine offers, physical holdings acquired and registered for export prior to the imposition of the Argentine minimum export clearing price to Brazil, were from US\$0.49 to US\$3.72 per metric ton (or US\$0.01 to US\$0.10 per bushel) cheaper than the heavily subsidized French wheat. The EEC export subsidy for wheat is now producing the subsidy or price-discounted competition for wheat export sales from both Argentina and Turkey. I suspect that such subsidy or price-discounted competition will only be fiercer in the coming months, particularly when the wheat boards of both Australia and Canada begin to negotiate seriously for export sales under the mounting pressures of record wheat production this year in both countries.

I appreciate having the opportunity to report to you periodically on the development in the international market for wheat, and appreciate the commitment from you and Ambassador Wolff to proceed with the announcement of our complaint in the FEDERAL REGISTER on December 22, 1978, for public hearings February 15 and 16, 1978, in Washington, D.C.

Sincerely,

MICHAEL L. HALL,
President.

GREAT PLAINS WHEAT INC.,
Washington, D.C., December 7, 1978.

Ambassador ROBERT S. STRAUSS,
Special Representative for Trade Negotiations,
1800 G Street, NW., Washington,
D.C. 20506.

DEAR MR. AMBASSADOR: On November 2, 1978, I submitted to your office a complaint under Section 301 of the U.S. Trade Act of 1974 about the trade disruptive practices of

the European Communities' use of export subsidies for making wheat sales to third-country markets. This complaint requested several immediate actions by the U.S. Government under the authority of Section 301, the most immediate of which was the request "... a public hearing under Section 301 (D)(2) of the U.S. Trade Act of 1974."

Notwithstanding my communications of November 14 and November 27 to you, both of which reiterated my request for a public hearing on this issue and which advised you of even greater export sales of subsidized European wheat to traditional U.S. foreign markets, there has been no official comment or reply from you or other officials of the Office of the Special Representative For Trade Negotiations.

Subsequent to my last communication of November 27 to you, an additional 50,000 tons (1.8 million bushels) of French wheat was sold to Brazil with an export subsidy in the neighborhood of US\$120.00 per metric ton (US\$3.27 per bushel). Consequently, well over 125,000 tons (or 4.6 million bushels) of U.S. wheat were rejected. The French wheat was sold at prices between US\$135.00 to US\$136.00 per ton (or US\$3.67 to US\$3.70 per bushel) f.o.b. French ports compared to the rejected U.S. wheat offers at between US\$142.64 to US\$143.00 (US\$3.88 to US\$3.89 per bushel) f.o.b. Gulf ports. With the assistance of the EEC wheat export subsidy, French wheat was not only unfairly priced competitively with U.S. wheat, in fact, French wheat was priced between US\$7.64 to US\$8.00 (or about US\$0.21 to US\$0.22 per bushel) cheaper than the export offer of higher quality U.S. wheat viz-a-vis the lower quality European wheat.

A further 58,000 tons (2.1 million bushels) of French wheat were offered against the Brazilian Wheat Board tender on December 3, 1978, all of which was rejected. Nevertheless, the French wheat was offered at US\$134.90 to US\$139.95 per metric ton (or about US\$3.67 to US\$3.81 per bushel) f.o.b. French ports for shipment during the January-March 1979 period. The Brazilian Wheat Board purchased 125,000 tons (or about 4.6 million bushels) of U.S. Hard Winter wheat at prices in the range of US\$141.49 to US\$141.99 per metric ton (or US\$3.85 to US\$3.86 per bushel) f.o.b. Gulf ports for the January-March 1979 shipping period. The Brazilian Wheat Board rejected the French wheats simply because of the pressing requirement to receive the higher quality U.S. wheats for blending purposes with both the much lower quality Brazilian and French wheat, particularly because of the heavy purchases of the subsidized French wheats for the January-March 1979 period. The important feature of this transaction, however, is that the heavily subsidized European wheats were still approximately US\$2.05 to US\$6.59 per metric ton (or US\$0.06 to US\$0.18 per bushel) cheaper than the higher quality U.S. wheat.

There has been additional export sales of European wheat to other destinations in recent weeks, the most notable of which is the sale yesterday of 202,500 metric tons (or 7.4 million bushels) to Morocco at an average price of about US\$130.00 per metric ton (or US\$3.54 per bushel) f.o.b. French ports. Little, if any, U.S. wheats were offered, notwithstanding the Moroccan request for U.S. wheat, because of the obviously cheaper price of French wheat with the assistance of heavy wheat export subsidies and the more favorable freight rate between French and

Moroccan ports viz-a-vis Gulf ports. Moreover, there has been a significant quantity of French wheat sold recently to Poland by minor grain exporting firms in France and other EEC countries, the data and details of which are not yet known. Nevertheless, the sales of French wheat to Poland are being made solely because of the EEC export subsidy of about US\$120.00 per metric ton (or US\$3.27 per bushel) in order to bring the higher domestic prices for EEC wheat down to the level of wheat prices on the international market.

In light of the sustained wheat expansion program by the EEC Commission made only possible by the use of inordinately high wheat export subsidies to all destinations, it is imperative that the Section 301 complaint by Great Plains Wheat be immediately considered with a view toward an immediate announcement the requested public hearings on this issue. The data and information prepared and submitted to your office in four separate communications fully warrant the attention of the appropriate officials in the Office of the Special Trade Representative. The first step is to proceed with the public hearings on the injurious actions by the European Communities in subsidizing wheat exports to the displacement and disruption of U.S. wheat export sales to traditional U.S. markets.

Sincerely,

MICHAEL L. HALL,
President.

GREAT PLAINS WHEAT INC.,

Washington, D.C., November 27, 1978.

Ambassador ROBERT S. STRAUSS,
Special Representative For Trade Negotiations,
1800 G Street NW., Washington,
D.C. 20506.

DEAR MR. AMBASSADOR: On November 3, 1978, I submitted to your office a complaint under Section 301 of the U.S. Trade Act of 1974 about the use of EEC export subsidies for making wheat sales to third-country markets. Subsequent to filing that Section 301 Complaint, I sent a telex on November 14, 1978, to you at the U.S. Mission to the European Offices of the U.N. and Other International Organizations in Geneva, Switzerland, about the continuation of the EEC use of export subsidies to disrupt and displace U.S. wheat export sales to additional third-country markets.

I would like for you to have the following information in order to keep you current on the EEC subsidized wheat export program and to keep current the Section 301 Complaint by Great Plains Wheat submitted to your office for immediate consideration and action.

1. An additional heavily subsidized sale of 72,000 tons of European wheat to Brazil with the assistance of an export subsidy of about US\$3.25 per bushel, displacing sizable offers of U.S. wheat because the European wheats were priced about US\$0.33 per bushel cheaper than U.S. wheat. A total of 237,000 tons of heavily subsidized European wheat has now been sold to Brazil, a market with which there is little or no history of European wheat trading relations.

2. In a very surprisingly unfair pricing development, 60,000 tons of European wheat flour was sold to Sri Lanka with an export subsidy as high as US\$185.00 per ton (or an equivalent of US\$5.65 per bushel).

3. Commercial and trade contracts report that EEC commission officials are tacitly encouraging a vigorous export sales pro-

gram for European wheat, all of which suggest that the commission fully plans to continue to provide whatever level of subsidy necessary to make the very high priced European wheats competitive with the price of more efficient wheats produced in and exported from the major exporting countries.

I realize that you and your senior staff officials have been extremely busy during the past several weeks with many agricultural and industrial trade issues. While genuinely appreciating your efficacious representation on behalf of U.S. wheat farmers to Vice President Finn Gundelach about the EEC use of wheat export subsidies, I urge you to consider our November 2, 1978, request for "... a public hearing under Section 301(d)(2) of the U.S. Trade Act of 1974". Moreover, such a public hearing, the announcement of which to be held as soon as possible should be issued now, will serve well both the U.S. Government and wheat industry in placing into perspective the injurious actions of the European Communities to American wheat farmers.

With best regards,

Sincerely,

MICHAEL L. HALL,
President.

NOVEMBER 14, 1978.

Ambassador ROBERT S. STRAUSS,
U.S. Mission to the European Office of the
U.N. and Other International Organizations,
Telex 22103 USM 10-CH

DEAR MR. AMBASSADOR: On November 2, 1978 I submitted to your office a complaint under Section 301 of the U.S. Trade Act of 1974 about the use of EEC export subsidies for making wheat sales to third country markets. Subsequent to that date and at the initiation of several EEC commission officials I met with several commission officials on November 9, 1978 to discuss informally the EEC wheat export subsidy practice, particularly at this crucial concluding period of the GATT/MTN negotiations and the UNCTAD trade wheat negotiations.

Subsequent to the filing of my Section 301 complaint, further quantities of European wheat have been sold to several third country markets—all to the displacement of U.S. wheat export sales and to the disadvantage of U.S. wheat farmers. In your scheduled discussions with EEC officials and in your deliberations about concluding the current trade negotiations and the wheat negotiations, I would like for you to know the following information in addition to the data presented in my Section 301 complaint of November 2:

1. With the Assistance of an effective subsidy of about U.S. DLR. 5.64, 11,750 tons of EEC wheat flour was just sold to Chile and an additional 25,000 tons of EEC Wheat flour are now being negotiated for sale to Chile and with the assistance of an excessively high export subsidy.

2. Just overnight there were additional sales of EEC wheat to Brazil. 75,000 of European Wheat was sold for shipment during January/March 1979 at FOB French ports in the range of US DLR. 132.75 to US DLR. 133.96 P.M.T. All U.S. Wheat Export offers against the Brazilian tender were rejected, and the U.S. Wheats were offered at prices between U.S. DLR. 143.00 to U.S. DLR. 144.00 per M.T. for shipment during January/March 1979.

3. A total of 165,000 tons of EEC wheat has now been sold to Brazil with export subsidies as high as U.S. DLR. 120.00 per M.T.

In addition these EEC wheat sales have been made at prices about U.S. DLR 10.00 per M.T. cheaper than comparable U.S. wheat export offers.

I fully suspect that further sales of sizable quantities of EEC wheat will be made in the coming months at highly subsidized export prices. Under these circumstances, it appears exceedingly inappropriate to continue to negotiate with EEC officials about various issues, particularly the issues of export subsidies and an international wheat agreement. U.S. wheat farmers are well aware of the unfair wheat trading practices of the EEC Commission, and are fully committed to press vigorously ahead with the Section 301 complaint. In addition, any results of the current GATT/MTN and the UNCTAD Trade Wheat Negotiations will be judged by U.S. wheat farmers against the current and anticipated unfair wheat export subsidies provided by the EEC commission to make European wheats unfairly competitive in various third country markets.

MICHAEL L. HALL,
President,
Great Plains Wheat, Inc.

HEARINGS

1. The complainant has requested that hearings be held on this matter. Such hearings will be held on *February 15, 1979* and, if necessary, will continue on *February 16, 1979*. The Hearings are to be held at the office of the Special Representative for Trade Negotiations, 1800 G Street NW., Washington, D.C. Room 730, beginning at 10 a.m.

2. Requests to present oral testimony and accompanying briefs must be received on or before *February 9, 1979*. Written briefs from those persons not wishing to present oral testimony should be received in the Office of the Special Representative for Trade Negotiations on or before the date of the hearing, in order to be considered by the Section 301 Committee.

Interested persons are advised to refer to the regulations promulgated by the Office of the Special Representative for Trade Negotiations covering procedures to be followed in all Section 301 proceedings (15 CFR 2006 as amended by FEDERAL REGISTER notice of Tuesday, October 18, 1977, page 55611). Please note that all communications to the Chairman of the Section 301 Committee should be addressed to the Office of the Special Representative for Trade Negotiations, Room 715, 1800 G Street N.W., Washington, D.C. 20506.

(a) *Submission of briefs requests to present oral testimony.* Requests for oral testimony and submission of writing briefs should conform to the procedures set forth in 15 CFR 2006.6 and 2006.7 as amended.

(b) *Rebuttal briefs.* In order to assure parties an opportunity to contest information provided by other interested parties in the written briefs and the oral testimony, rebuttal briefs

may be filed by any party within 15 days after the transcript of the hearing becomes available.

(c) *Attendance at hearings.* The hearings will be open to the public.

SHIRLEY A. COFFIELD,
Chairman, 301 Committee,
Office of the Special Representative for Trade Negotiations.

[FR Doc. 78-35834 Filed 12-21-78; 8:45 am]

[7708-01-M]

PENSION BENEFIT GUARANTY CORPORATION

IMPROVING QUALITY OF REGULATIONS

Semiannual Agenda of Significant Regulations Under Development

Under the President's Order on improving government regulations (Executive Order 12044, 43 F.R. 12661 (March 24, 1978)), each Executive Agency is required to publish semiannually an agenda of significant regulations under development or scheduled to be reviewed by the agency. The Pension Benefit Guaranty Corporation ("PBGC") currently has under development a number of regulations, nine of which have been designated "significant" by PBGC in accordance with its Statement of Policy and Procedures implementing the Executive Order (43 F.R. 58237 (December 13, 1978)). (For the reasons set forth in the Statement of Policy and Procedures, the PBGC has not as yet scheduled any of its existing regulations for review.) In accordance with the Executive Order, this notice contains a brief description of each significant regulation and sets forth certain other background information pertinent to each. Interested members of the public with questions or comments concerning these regulations are invited to write or telephone the PBGC contact designated for each regulation. The PBGC's mailing address is 2020 K St., N.W., Washington, D.C. 20006.

1. NOTIFICATION REQUIREMENTS FOR REPORTABLE EVENTS AND ESTABLISHMENT OF NEW REPORTABLE EVENTS

DESCRIPTION. Section 4043(a) of the Employee Retirement Income Security Act of 1974 ("ERISA") requires a plan administrator to file a notice with the PBGC within 30 days after he or she knows or has reason to know of the occurrence of an event listed in section 4043(b). Section 4043(b) sets forth eight specific events, the occurrence of which might indicate the need to terminate a pension plan. In addition, section 4043(b)(9) gives the PBGC authority to prescribe other events which may be indicative of a

need to terminate a pension plan and of which PBGC must be notified.

On November 16, 1977, the PBGC published for comment a proposed rule (42 F.R. 59285) setting forth the reporting requirements under section 4043, including when those requirements will be waived, and establishing new reportable events under section 4043(b)(9). (Correction published on December 1, 1977 at 42 F.R. 61051.) Comments from the public were received and reviewed by PBGC staff, and the PBGC is currently drafting the final regulation. It is anticipated that the final regulation will be very similar to the proposal, although the information requirements for the notification of a reportable event will be reduced.

NEED. This regulation is needed so that plan administrators will know when they must notify the PBGC of the occurrence of a reportable event and what documentation must be submitted with the notice. In addition, the PBGC's experience over the past four years suggests that there are events other than those specifically listed in section 4043(b) which may indicate the need to terminate a plan, and thus the effective administration of Title IV of ERISA requires that these events be promulgated as additional reportable events.

LEGAL BASIS. ERISA sections 4002(b)(3), 4043 and 4065; 29 U.S.C. 1302(b)(3), 1343 and 1365.

REGULATORY ANALYSIS. Not required.

AGENCY CONTACT. Mr. David Weingarten, Attorney, Office of the General Counsel, 202-254-3010.

2. PROPOSED RULES FOR DETERMINING AND COLLECTING EMPLOYER LIABILITY

DESCRIPTION. Under section 4062 of ERISA, a single employer who maintains a pension plan covered by Title IV that terminates without sufficient assets to pay all benefits guaranteed by PBGC is liable to the PBGC for the lesser of the plan asset insufficiency or 30% of the employer's net worth. Net worth is to be determined on whatever basis PBGC believes best reflects an employer's operations and prospects at the time of the determination. Furthermore, the PBGC is authorized under section 4067 of ERISA to arrange for deferred payment of employer liability on whatever terms it deems appropriate and equitable.

The PBGC is currently developing a proposed rule dealing with these issues that will be published for public comment. The regulation will, among other things: define net worth; set forth the principal measures of fair market value; set forth the data requirements for substantiating fair market value; establish the date used

in a net worth determination; and set forth the guidelines PBGC will follow in granting deferred payment terms.

NEED. This regulation is needed in order to advise employers who maintain pension plans how the PBGC will compute their net worth, and ultimately their liability under section 4062, in the event of plan termination. It is also needed so that employers will be aware of the circumstances under which the PBGC will allow deferred payment of their liability and the general terms of deferred payment.

LEGAL BASIS. ERISA SECTIONS 4002(b)(3), 4062, AND 4067; 29 U.S.C. 1302(b)(3), 1362 AND 1367.

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Mr. Seth Tievsky, Attorney, Office of the General Counsel, 202-254-3010.

3. PROPOSED RULES FOR ESTABLISHING PROSPECTIVE INTEREST RATES FOR VALUING PLAN BENEFITS (PROPOSED AMENDMENT TO INTERIM REGULATION ON VALUING PLAN BENEFITS)

DESCRIPTION. Upon plan termination, it is necessary to value plan assets and benefits in order to determine whether the plan has sufficient assets to pay guaranteed benefits. Under the PBGC's proposed rule for determining plan sufficiency (41 FR 48504 (November 3, 1976)), the plan administrator must advise the PBGC at the time he files a notice of intent to terminate the plan whether or not he will attempt to show that the plan is sufficient. Thus, the plan administrator must be able to compute the plan assets and liabilities at that time.¹

In addition, under the proposed rule for determining plan sufficiency, a plan sponsor may choose to ensure plan sufficiency by making an irrevocable commitment prior to the date of plan termination to pay into the plan the amount needed to make the plan sufficient. Before deciding whether to make such a commitment, a plan sponsor would want to know with as much accuracy as possible the amount of the plan underfunding; and this, of course, would require a valuation of plan assets and benefits.

Under the PBGC's Interim Regulation on Valuing Plan Benefits (29 CFR, Part 2610), the interest rates to be used in the valuation have been published on a quarterly basis by the PBGC. These rates have been derived from insurance industry price data, and because this data is collected quarterly and received by the PBGC after the beginning of the quarter to which the interest rates apply, the

rates have always been published after the period of time for which they are to be used.

The PBGC is currently developing a method of establishing interest rates on a prospective basis. This will enable PBGC to publish its rates prior to the period of time for which they are to be in effect. PBGC plans to issue a proposed amendment to the Valuation of Plan Benefits regulation describing the process it will use to determine prospective interest rates, and then to amend the regulation periodically (but generally not more frequently than monthly) to establish the rates for future periods of time. This system will enable interested persons to know the interest rates for valuing benefits and thus to perform the valuation prior to the date of plan termination.

NEED. The vast majority of plan terminations processed by PBGC involve sufficient plans. The PBGC expects that the new procedures in its regulation on determining plan sufficiency will simplify and speed up the handling of these cases. However, these procedures are dependent on a plan administrator (and, when applicable, a plan sponsor) being able to value plan assets and liabilities before the date of plan termination. This regulation, which will enable PBGC to issue interest rates before the period of time for which they are applicable, is needed so that plan benefits can be valued prospectively.

LEGAL BASIS. ERISA sections 4002(b)(3), 4044 and 4062(b)(1)(A); 29 U.S.C. 1302(b)(3), 1344, and 1362(b)(1)(A).

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Ms. Judith Goldstein, Deputy Assistant General Counsel, Office of the General Counsel, 202-254-4895.

4. PROPOSED RULES GOVERNING THE REVERSION OF EXCESS PLAN ASSETS

DESCRIPTION. Numerous questions have arisen concerning the proper distribution of excess plan assets remaining after the satisfaction of all plan liabilities to participants and beneficiaries upon plan termination. Section 4044(d) of ERISA provides an exception to the general rule contained in section 403 that plan assets shall never inure to the benefit of the employer. Specifically, section 4044(d)(1) provides that any residual plan assets may be distributed to the employer if 1) all plan benefits have been paid, 2) the plan provides for such a distribution, and 3) the distribution is not otherwise unlawful. However, any residual assets attributable to employee contributions must be distributed to plan participants or beneficiaries (section 4044(d)(2)).

One of the major problems in applying section 4044(d) is determining when a plan "provides for" the distribution of excess assets to the employer. Therefore, the PBGC will issue a proposed regulation setting forth rules for applying this requirement (and the other two requirements). In addition, the regulation will address the issues that arise under a contributory plan, such as determining what portion of excess assets are attributable to employee contributions and to which employees and in what manner such assets should be distributed.

NEED. This regulation is needed in order to help resolve disputes among employers, participants and plan administrators over the correct distribution of residual plan assets.

LEGAL BASIS. ERISA sections 4002(b)(3) and 4044(d); 29 U.S.C. 1302(b)(3) and 1344(d).

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Mr. Steven Schreiber, Attorney, Office of the General Counsel, 202-254-3010.

5. PROPOSED RULES ON THE ALLOCATION OF EMPLOYER LIABILITY AMONG EMPLOYERS IN A MULTIPLE EMPLOYER OR MULTIEMPLOYER PLAN.

DESCRIPTION. Section 4064 of ERISA contains the employer liability provisions applicable in cases involving the termination of a plan maintained by more than one employer. This section imposes liability on each employer who maintains the plan at the time the plan terminates and each employer who contributed to the plan within the five years preceding the date of termination. The general rule is that each employer's liability is a pro rata share of the total plan insufficiency determined according to each employer's required rate of contributions during the five years preceding plan termination. In a declining industry, this method of allocating employer liability may create a hardship for the employer who remains in the plan until the date of termination.

However, section 4064 also gives PBGC the authority to determine the liability of each employer "on any other equitable basis prescribed by the [PBGC] in regulations." Accordingly, the PBGC plans to promulgate regulation which will set forth an alternate method for allocating employer liability under section 4064 and will also contain criteria for using this alternate allocation rather than the allocation prescribed in section 4064.

NEED. Cases have arisen where the imposition of employer liability in accordance with the formula contained in section 4064 appears to produce an unjustifiable hardship for certain employers. However, in order to allocate

¹Under the PBGC's Valuation of Plan Assets regulation, 29 CFR, Part 2611, it is already possible to value plan assets prior to plan termination.

liability in some other fashion under section 4064, that alternate method of allocation must, pursuant to section 4064, be promulgated as a regulation.

LEGAL BASIS. ERISA section 4002(b)(3) and 4064(b); 29 U.S.C. 1302(b)(3) and 1364(b).

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Mr. David Weingarten, Attorney, Office of the General Counsel, 202-254-3010.

6. PROPOSED RULES FOR MULTIEMPLOYER MERGERS, SPINOFFS AND TRANSFERS OF ASSETS OR LIABILITIES UNDER SECTION 208 OF ERISA

DESCRIPTION. Section 208 of ERISA and section 414(1) of the Internal Revenue Code (the "Code") provide that a pension plan may not merge or consolidate with, or transfer its assets or liabilities to, another plan unless plan participants would, in the event of plan termination immediately after the merger, consolidation or transfer, receive a benefit equal to or greater than the benefit they would have received had the plan terminated just prior to the merger, consolidation or transfer. In addition, these sections provide that this rule will apply in the case of multiemployer plans only to the extent determined by PBGC.

PBGC recognizes that if the rule of sections 208 and 414(1) were made fully applicable to multiemployer plan mergers, spinoffs and transfers, such transactions would become administratively difficult, very expensive, and in some situations impossible. On the other hand, PBGC recognizes that there is a need for some protection of the benefits of multiemployer plan participants in these situations. Also, if plan mergers, spinoffs and transfers of assets or liabilities were not regulated in any way, there would be a significant opportunity for abuse of the plan termination insurance program. Accordingly, PBGC is currently developing a regulation that will limit the application of sections 208 and 414(1) in the multiemployer plan context so as not to unduly impede multiemployer plan mergers, spinoffs and transfers, while at the same time protecting the benefits of plan participants and preventing abuses of the termination insurance program.

NEED. This regulation is needed to provide guidance to multiemployer plans that are considering mergers, spinoffs or transfers of assets or liabilities as to the extent to which ERISA section 208 and Code section 414(1) will apply to them.

LEGAL BASIS. ERISA sections 208, 4002(b)(3) and 4044; 29 U.S.C. 1058, 1302(b)(3) and 1344.

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Mr. Mark Blank, Attorney, Office of the General Counsel, 202-254-3010.

7. RULES FOR DETERMINING PLAN SUFFICIENCY AND FOR TERMINATING SUFFICIENT PLANS

DESCRIPTION. Under section 4041(b) of ERISA, the PBGC must determine whether the assets of a terminating plan are sufficient to pay all guaranteed benefits provided under the plan. If they are, the plan administrator is so notified and may then proceed with the plan termination "in a manner consistent with" Subtitle C of Title IV of ERISA (section 4041(a)). However, the statute does not specify how plan sufficiency is to be determined or how the affairs of a sufficient plan are to be wound up.

Therefore, on November 3, 1976, the PBGC published (41 FR 48504) a proposed regulation on the "Determination of Plan Sufficiency and Termination of Sufficient Plans." This regulation involves a number of important policy issues and also entails other regulatory changes (see item #3 of this Notice) needed to implement the procedures set forth in the proposal. The PBGC is now preparing to issue the regulation in final form, and it will be similar in substance to the proposal.

NEED. Currently the processing of sufficient plan terminations (which greatly exceed the number of insufficient plan terminations) takes a considerable length of time, in part, because of uncertainty in some cases as to whether or not a plan is sufficient, and in part, because of the lack of well-defined procedures for winding up the affairs of termination sufficient plans. This regulation will substantially resolve both problems, and thus should reduce significantly the time needed to process the termination of a sufficient plan.

LEGAL BASIS. ERISA sections 4002(b)(3), 4041 and 4044; 29 U.S.C. 1302(b)(3), 1341 and 1344.

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Ms. Judith R. Goldstein, Deputy Assistant General Counsel, Office of the General Counsel, 202-254-4895.

8. PROPOSED RULES FOR VALUING AND ALLOCATING GROUP INSURANCE CONTRACTS (AMENDMENTS TO THE ALLOCATION OF ASSETS AND VALUATION OF PLAN ASSETS REGULATIONS)

DESCRIPTION. Upon termination of a pension plan covered under Title IV of ERISA its assets must be valued and allocated in accordance with section 4044 of ERISA, in order to determine whether the plan is sufficient. Because of the unique nature of insurance contracts, their value cannot properly be

measured in terms of fair market value, the way other assets are valued. (29 CFR, Part 2611, Valuation of Plan Assets.) Accordingly, on April 18, 1977, the PBGC published (42 Fed. Reg. 20158) a proposed regulation setting forth the rules for valuing insurance contracts as plan assets. At the same time, PBGC published (42 Fed. Reg. 20156) proposed amendments to its Allocation of Assets regulation (29 CFR, Part 2608) needed to accommodate the new valuation rules for insurance contracts.

Comments on these proposals have been received and analyzed by the PBGC, and the PBGC is currently preparing to finalize portions of the proposals and to issue a new proposal dealing with the remainder. Specifically, the PBGC plans to issue a final rule amending its Valuation of Plan Assets, and Allocation of Assets regulations to include the major portion of the rules needed for valuing insurance contracts and allocating the assets of plans with such contracts. These rules are expected to be similar to the proposed rules, with certain minor changes in response to public comment. In addition, amendments to the two regulations will again be issued in proposed form and will cover the treatment of contracts containing participation rights and other features of insurance contracts that cannot be allocated in accordance with the current regulation.

NEED. These amendments are needed in order to enable plan administrators to value and allocate correctly insurance contracts held as plan assets.

LEGAL BASIS. ERISA sections 4002(b)(3), 4041, 4044, and 4062(b)(1)(B); 29 U.S.C. 1302(b)(3), 1341, 1344, and 1362(b)(1)(B).

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Ms. Judith F. Mazo, Special Counsel, Office of the General Counsel, 202-254-4868.

9. PROPOSED RULES FOR DISTINGUISHING BETWEEN A SINGLE PLAN AND AN AGGREGATE OF SINGLE PLANS

DESCRIPTION. The PBGC's guarantee of pension benefits only becomes operative upon the termination of a pension plan (section 4022(a) of ERISA). The Withdrawal of an employer from a plan to which more than one employer contributes does not give rise to the PBGC's guarantee of benefits, although it may result in employer liability under section 4063 of ERISA. In a plan to which more than one employer contributes; the question of whether a cessation of contributions by an employer results in a plan termination or merely an employer withdrawal turns on whether the plan is actually an aggregate of single plans

rather than one plan. This determination is not always an easy one to make. The existence of one or several plan documents, the existence of different benefit structures applicable to different participant groups, the nature of plan accounting, the existence of restrictions on a plan's obligations to participants upon the cessation of contributions by their employer, and past plan practice are some of the factors that must be considered in distinguishing between a single plan and an aggregate of plans. PBGC has by now dealt with a number of cases involving this issue and has therefore developed a good deal of experience in assessing the factors relevant to this determination. Based on this experience and in recognition of the multiplicity of factors potentially involved in this determination, the PBGC plans to issue for public comment a proposed rule setting forth the criteria to be applied in distinguishing between a single plan and an aggregate of plans.

NEED. The regulation is needed so that employers, plan participants and plan administrators will be able to determine when a cessation of contributions by an employer results in an insurable event and when it does not.

LEGAL BASIS. ERISA sections 4002(b)(3), 4022(a), 4063 and 4064; 29 U.S.C. 1302(b)(3), 1322(a), 1363 and 1364.

REGULATORY ANALYSIS. Not required.

PBGC CONTACT. Mr. David Levin, Attorney, Office of the General Counsel, 202-254-4895.

Issued in Washington, D.C. this 18th day of December, 1978.

MATTHEW M. LIND,
Executive Director, Pension
Benefit Guaranty Corporation.

[FR Doc. 78-35527 Filed 12-21-78; 8:45 am]

[8025-01-M]

SMALL BUSINESS ADMINISTRATION

[Proposed License No. 06/06-0210]

SOUTHWEST FINANCIAL CORP.

Application for a License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration (SBA) pursuant to § 107.102 of the regulations governing small business investment companies (13 CFR 107.102 (1978)), under the name of Southwest Financial Corporation, Suite 404, 400 Pile Place, Clovis, New Mexico 88101, for a license to operate as a small business company (SBIC) under the provisions of the Small Business Investment Act of

1958, as amended (the Act) (15 U.S.C. 661 et seq.), and the rules and regulations promulgated thereunder.

The proposed officers, directors and shareholders are as follows:

William T. Battin, 1404 Piedmont, Clovis, New Mexico 88101, President, Treasurer, Director, 33.33% shareholder.

Gabriel E. Parson, Rt. II, Clovis, New Mexico 88101, Vice President, Secretary, Director, 33.33% shareholder.

James B. Moss, 3201 Axtell, Clovis, New Mexico 88101, Vice President, Director, 33.33% shareholder.

There are two classes of stock authorized: (1) One million shares of common stock, par value \$1 per share; and, (2) 10,000 shares of preferred stock, par value \$100 per share. Each of the original shareholders intends to purchase 101,000 shares of the common stock at par, with the resulting initial private capital of \$303,000. It is represented that said private capital will be increased to at least \$500,000 within one year from the date of licensing.

The Applicant Licensee will emphasize, as much as is practicable equity investments with no particular concentration in any one industry.

Matters involved in SBA's consideration of the application include the general business reputation and character of shareholders and management, and the probability of successful operation of the new company in accordance with the Act and Regulations.

Notice is further given that any person may, not later than January 8, 1979, submit to SBA, in writing, comments on the proposed licensing of this company. Any such communications should be addressed to: Associate Administrator for Finance and Investment, Small Business Administration, 1441 "L" Street, NW., Washington, D.C. 20416.

A copy of this notice shall be published by the Applicant in a newspaper of general circulation in Clovis, New Mexico.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: December 15, 1978.

PETER F. McNEISH,
Deputy Associate
Administrator for Investment.

[FR Doc. 78-35579 Filed 12-21-78; 8:45 am]

[4710-02-M]

DEPARTMENT OF STATE

Agency for International Development

BOARD FOR INTERNATIONAL FOOD AND AGRICULTURAL DEVELOPMENT

Meeting

Pursuant to Executive Order 11769 and the provisions of Section 10(a), (2), Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given of the twenty-fifth meeting of the Board for International Food and Agricultural Development (BIFAD) on January 17, 1979.

The purpose of this meeting is to: Receive and discuss the progress reports of the Joint Research Committee (JRC) and the Joint Committee for Agricultural Development (JCAD); discuss approval of amended JRC Guidelines and Evaluation Process; discuss baseline study recommendations and first cut on the returns of the Strengthening Grants; discuss five-year budget projections; discuss changes in the Collaborative Research Support Program (CRSP) guidelines to assure federal agency participation; discuss Overseas Private Investment Corporation (OPIC) and the Food and Agricultural Organization briefings; and to hear various other reports and activities.

The meeting will begin at 10:00 a.m., adjourn at 4:00 p.m., and will be held in Room 1107, State Department Building, 22nd and C Streets, NW., Washington, D.C. The meeting is open to the public. Any interested person may attend, may file written statements with the Board before or after the meeting, or may present oral statements in accordance with procedures established by the Board, and to the extent the time available for the meeting permits. An escort from the "C" Street Information Desk (Diplomatic Entrance) will conduct you to the meeting room.

Dr. Erven J. Long, Director, Office of Title XII Coordination and University Relations, Development, Support Bureau, A.I.D., is designated as A.I.D. Advisory Committee Representative at the meeting. It is suggested that those desiring further information write to him in care of the Agency for International Development, State Department, Washington, D.C. 20523, or telephone him at (703) 235-2243.

Dated: December 19, 1978.

ERVEN J. LONG,
A.I.D. Advisory Committee Representative,
Board for International Food and Agricultural Development.

[FR Doc. 78-35643 Filed 12-21-78; 8:45 am]

[4710-02-M]

JOINT RESEARCH COMMITTEE OF THE BOARD
FOR INTERNATIONAL FOOD AND AGRICUL-
TURAL DEVELOPMENT

Meeting

Pursuant to Executive Order 11769 and the provisions of Section 10(a), (2) Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given of the nineteenth meeting of the Joint Research Committee of the Board for International Food and Agricultural Development on January 9 and 10, 1979.

The purpose of the meeting is to: review proposed amendments to the Guidelines of the Joint Research Committee concerning procedures for planning and implementing collaborative research support programs (CRSPs) with Title XII universities; review progress of CRSPs being planned and implemented; and to discuss long-term research programs for overcoming constraints to increasing production and improving consumption of food in developing countries.

The meeting will convene at 9:00 a.m. and adjourn at 5:00 p.m. on January 9 and 10, 1979. The meeting will be held in the Dynasty Room of the Holiday Inn, 1850 N. Ft. Myer Drive, Arlington, Virginia, 22209. The meeting is open to the public. Any interested person may attend, may file written statements with the Committee before or after the meeting, or may present oral statements in accordance with procedures established by the Committee, and to the extent the time available for the meeting permits.

Dr. Erven J. Long, Office of Title XII Coordination and University Relations, Development Support Bureau, is designated A.I.D. Advisory Committee Representative at the meeting. It is suggested that those desiring further information write to him in care of the Agency for International Development, State Department, Washington, D.C. 20523, or telephone him at 703-235-2243.

Dated: December 19, 1978.

ERVEN J. LONG,
A.I.D. Advisory Committee Rep-
resentative, Joint Research
Committee, Board for Interna-
tional Food and Agricultural
Development.

[FR Doc. 78-35644 Filed 12-21-78; 8:45 am]

[4710-02-M]

JOINT COMMITTEE FOR AGRICULTURAL DE-
VELOPMENT OF THE BOARD FOR INTERNA-
TIONAL FOOD AND AGRICULTURAL DEVEL-
OPMENT

Meeting

Pursuant to Executive Order 11769 and the provisions of Section 10(a), (2) Pub. L. 92-463, Federal Advisory Committee Act, notice is hereby given of the meeting of the Joint Committee on Agricultural Development (JCAD) of the Board for International Food and Agricultural Development (BIFAD) on January 8 and 9, 1979.

The purpose of the meeting is to: discuss alternatives for the organization of the JCAD agenda; discuss plans for participation in the review of Country Development Strategy Statements (CDSS); report on the University Strengthening program; discuss progress report on the status of baseline studies; discuss plans for Title XII visits to missions; and consider other business brought before the Committee.

The meeting on January 8, 1979, will convene in Regional Work Groups (RWGs): Africa RWG at 9:30 a.m. in Room 2941, New State Department Bldg.; Asia RWG at 9:30 a.m. in Room 609 Rosslyn Plaza Bldg., 1601 North Kent Street, Rosslyn, Virginia, Near East RWG at 9:30 a.m. in Room 6484, New State Department Bldg.; and Latin America RWG at 9:30 a.m. in Room 2242 New State Department Bldg. The meeting on January 9, 1979, will convene from 9:00 a.m. to 5:00 p.m. in the Arlington Room of the Quality Inn, Pentagon City, 300 Army-Navy Drive, Arlington, Virginia, 22202. The meeting is open to the public. Any interested person may attend, may file written statements with the Committee before or after the meeting, or may present oral statements in accordance with procedures established by the Committee, and to the extent the time available for the meeting permits.

Dr. Carl E. Ferguson, Office of Title XII Coordination, Development Support Bureau, is designated A.I.D. Advisory Committee Representative at the meeting. It is suggested that those desiring further information write to him in care of the Agency for International Development, State Department, Washington, D.C. 20523, or telephone him at 703-235-9054.

Dated: December 19, 1978.

ERVEN J. LONG,
A.I.D. Advisory Committee Rep-
resentative, Joint Committee
on Agricultural Development,
Board for International Food
and Agricultural Development.

[FR Doc. 78-35645 Filed 12-21-78; 8:45 am]

[4710-09-M]

Office of the Secretary

[Public Notice 643]

BUREAU OF OCEANS AND INTERNATIONAL
ENVIRONMENTAL AND SCIENTIFIC AFFAIRSAvailability of Draft Environmental Impact
Statement on Narcotics Control in Mexico

Pursuant to Section 102(2)(c) of the National Environmental Policy Act of 1969, the U.S. Department of State has prepared a Draft Environmental Impact Statement on Narcotics Control in Mexico, dated December 22, 1978. The Draft EIS considers the environmental effects in the United States of the joint United States Government-Government of Mexico program to control the production and trafficking of illicit narcotics in Mexico.

Copies of the Draft EIS may be obtained by writing to William H. Mansfield, Office of Environmental Affairs, Department of State, Room 7820, Washington, D.C. 20520. Written comments on the draft EIS should be submitted to Mr. Mansfield no later than February 8, 1979.

The Department has also prepared an Analysis of Narcotics Control in Mexico which discusses the environmental effects in Mexico associated with the joint narcotics control program. Copies of this document may be obtained at the address given above.

For the Secretary of State.

WILLIAM ALSTON HAYNE,
Deputy Assistant Secretary
for Environmental Affairs.

DECEMBER 19, 1978.

[FR Doc. 78-35882 Filed 12-21-78 10:25 am]

[7035-01-M]

INTERSTATE COMMERCE
COMMISSION

[Notice No. 764]

ASSIGNMENT OF HEARINGS

DECEMBER 19, 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.

No. MC 51146 (Sub-No. 611F), Schneider Transport, Inc., now being assigned for hearing on January 25, 1979, (1 day), in room No. 204A, Everett McKinley Dirksen Bldg., 219 South Dearborn St., Chicago, Illinois.

No. MC 115841 (Sub-No. 630F), Colonial Refrigerated Transportation, Inc., now assigned for hearing on January 9, 1979 at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 112595 (Sub-No. 78F), Ford Brothers, Inc., now assigned for hearing on January 10, 1979, at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 117786 (Sub No. 10F), Riley Whittle, Inc., now assigned for hearing on January 11, 1979, at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 128273 (Sub-No. 297), Midwestern Distribution, Inc., now assigned for hearing on January 12, 1979, at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 117416 (Sub-No. 58F), Newman And Pemberton Corporation, now assigned for hearing on January 15, 1979, at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 123069, Aller & Sharp, Inc., now assigned for hearing on January 17, 1979, at Columbus, Ohio and will be held in Room 235, Federal Building.

No. MC 140452 (Sub-No. 10F), Rose Brothers Trucking, Inc., now assigned for hearing on January 22, 1979, at Louisville, Kentucky, and will be held in Room 635, Post Office Building.

No. MC 114632 (Sub-No. 161F), Apple Lines, Inc., hearing now assigned April 23, 1979 in St. Paul, Minnesota (5) days, hearing room to be later designated.

No. MC 133937 (Sub-No. 25F), Carolina Cartage Company, Inc., now assigned for hearing on January 23, 1979, at Atlanta, Georgia and will be held in Room 305.

H. G. HOMME, Jr.,
Secretary.

[FR. Doc. 78-35678 Filed 12-21-78; 8:45 am]

[7035-01-M]

[Notice No. 763]

ASSIGNMENT OF HEARINGS

DECEMBER 19, 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.

Correction

No. MC 114301 (Sub-No. 96F), Delaware Express Co., Inc., now being assigned for hearing on January 31, 1979, at the Offices of the Interstate Commerce Commission, Washington, D.C., instead of continued hearing.

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 78-35679 Filed 12-21-78; 8:45 am]

[7035-01-M]

[Notice No. 144]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

The following publications include motor carrier, water carrier, broker, and freight forwarder transfer applications filed under Section 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act.

Each application (except as otherwise specifically noted) contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application.

Protests against approval of the application, which may include request for oral hearing, must be filed with the Commission within 30-days after the date of this publication. Failure seasonably to file a protest will be construed as a waiver of opposition and participation in the proceeding. A protest must be served upon applicants' representatives(s), or applicants (if no such representative is named), and the protestant must certify that such service has been made.

Unless otherwise specified, the signed original and six copies of the protest shall be filed with the Commission. All protests must specify with particularity the factual basis, and the section of the Act, or the applicable rule governing the proposed transfer which protestant believes would preclude approval of the application. If the protest contains a request for oral hearing, the request shall be supported by an explanation as to why the evidence sought to be presented cannot reasonably be submitted through the use of affidavits.

The operating rights set forth below are in synopsis form, but are deemed sufficient to place interested persons on notice of the proposed transfer.

MC-FC-77802, filed August 4, 1978. Transferee: IMPERIAL BULK CARRIERS, INC., 7061 S. Willow Springs Rd., Countryside, IL 60525. Transfer-

or: Fulsang's Motor Service, Inc., 7061 S. Willow Springs Rd., Countryside, IL 60525. Representative: William P. Jackson, Jr., Jackson, Jessup & Howard, P.C., 3426 N. Washington Blvd., P.O. Box 1240, Arlington, VA 22210. Authority sought for purchase by transferee of a portion of the operating rights of transferor as set forth in Certificate No. MC-120788 Sub 2 issued March 17, 1978, as follows: General commodities, in bulk, between points in Illinois. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under Section 210a(b).

MC-FC-77840, filed September 19, 1978. Transferee: JOHN N. SCHROCK, d.b.a. SCHROCK TRANSFER, 234 West Patriot Street, Somerset, PA 15501. Transferor: John Weller Schrock, d.b.a. Schrock Transfer, 234 Patriot Street, Somerset, PA 15501. Representative: William A. Gray, Esq., Wick, Vuono & Lavelle, 2310 Grant Building, Pittsburgh, PA 15219. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificates Nos. MC 42688, MC-42688 Sub 5 and MC-42688 Sub 6 issued May 13, 1960, December 1, 1966, and February 7, 1967, respectively, as follows: General commodities, between Somerset, PA and Johnstown, PA; between Garrett, PA and Hollsopple, PA; between Garrett, PA and Confluence, PA; from Confluence, PA to Somerset, PA, serving all intermediate points and the off-route points of Pinehall, Macdonald, Harrison, Acosta, Coal Junction, Jenners, and Trent, PA; Household goods as defined by the Commission, between Somerset, PA on the one hand, and, on the other points in Maryland, Ohio and West Virginia; such merchandise as is dealt in by wholesale retail, and chain grocery and food business houses and in connection therewith, equipment, materials and supplies used in the conduct of such business; and general commodities, with usual exceptions, between Somerset County Municipal Airport, in Somerset Township, Somerset County, PA on the one hand, and, on the other, points in Gedford, Cambria, Somerset, and Westmoreland Counties, PA and Alleghany County, MD; and Between Pittsburg, PA on the one hand, and, on the other, points in Somerset County, PA, Restricted to shipments having an immediately prior or immediately subsequent movement by rail. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77851, filed September 27, 1978. Transferee: G. M. RIDGE CORPORATION, 710 West Street, Brain-

tree, MA 02184. Transferor: Columbus Associates, Inc. (Mark N. Berman, Assignee for the benefit of creditors), 15-17 Stoughton Street, Dorchester District, Boston, MA 02125. Representatives: Mark N. Berman, Esq., Widett, Widett, Slater & Goldman, P.C., 100 Federal Street, Boston, MA 02110. Authority sought for purchase by transferee of the operating rights of transferor as set forth in License No. MC 130070, issued April 21, 1971, as follows: Passengers and their baggage, (1) in charter and special operations, between points in the United States, including Alaska and Hawaii. Restriction: The authority is restricted to the transportation of passengers who participate in tours which have been arranged by applicant, and who have a prior, subsequent or intervening movement by air, rail, or water carrier; (2) In round-trip charter and special operations, beginning and ending at points in MA, RI and NH, and extending to points in the United States, including AK, but excluding HA. Applicant is authorized to engage in the above-specified operations as a broker at Boston, MA. Transferee presently holds no authority from this Commission. Application has not been filed for temporary authority under section 210a(b).

MC-FC-77868, filed October 10, 1978. Transferee: DONALD J. HOHMAN, doing business as CROSS TRUCKING & STORAGE, 301 Regina Street, Pittsburgh, PA 15209. Transferor: Darby Transfer, Inc., 535 Forest Avenue, Pittsburgh, PA 15106. Representative: John A. Vuono, Esq., Stanley E. Levine, Esq., Attorneys for Transferee, 2310 Grant Building, Pittsburgh, PA 15219; Jerome Solomon, Esq., Attorney for Transferor, 3131 U.S. Steel Building, 600 Grant Street, Pittsburgh, PA 15219. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Certificates Nos. MC-2907 and MC-2907 Sub 5 issued September 29, 1966 as modified by order served July 6, 1968, and April 18, 1967, respectively, as follows: *Such commodities as are dealt in by wholesale, retail, and chain grocery stores, and materials, supplies, and equipment used or useful in connection therewith, between Pittsburgh, PA, on the one hand, and, on the other, points in Ohio east of U.S. Hwy 21, those in WV east of U.S. Hwy 21 and north of U.S. Hwy 60, and those in PA south of U.S. Hwy 322 and west of U.S. Hwy 220. New furniture, from McKees Rocks, PA, to points in that part of Ohio on and east of U.S. Hwy 21, points in that part of WV on and east of U.S. Hwy 21 and north of U.S. Hwy 60, and points in that part of PA on and south of U.S. Hwy 322 and on and east of U.S. Hwy 220, with no transportation for compensation on*

return except as otherwise authorized. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC 77910, filed November 7, 1978. Transferee: PEBBLE HAULERS, INC., 2630 Delta Drive, Colorado Springs, CO 80910. Transferor: Dalby Transfer and Storage, Inc., 641 Winters Drive, Colorado Springs, CO 80933. Representative: Raymond M. Kelley, Esq., 450 Capitol Life Center, Denver, CO 80203. Authority sought for purchase by transferee of a portion of the operating rights of transferor as set forth in Certificate No. MC-115860 Sub 6, issued January 16, 1976, as follows: Limestone and limestone (except cement), from points in El Paso and Teller Counties, CO to points in Arizona, Kansas, Nebraska, New Mexico, Oklahoma, Texas, Utah, and Wyoming, with no transportation for compensation on return except as otherwise authorized. Transferee presently holds no authority from this Commission. Application has been filed for temporary authority under section 210a(b).

MC-FC-77938, filed November 22, 1978. Transferee: PYNE FREIGHT LINES, INC., 15 South Keyser Avenue, P.O. Box 26, Taylor, PA 18517. Transferor: Mercury Freight, Inc., 15 South Keyser Avenue, P.O. Box 26, Taylor, PA 18517. Representative: Morton E. Kiel, Suite 6193, 5 World Trade Center, New York, NY 10048. Authority sought for purchase by transferee of the operating rights of transferor as set forth in Permit No. MC-142665 issued November 30, 1977, as follows: (1) Steel tubing and springs, welding materials and supplies, and anchor reels, (2) materials, equipment and supplies used in the manufacture, distribution, and installation of the commodities in (1) above, (except commodities in bulk, in tank vehicles), and (3) household goods as defined by the Commission, between points in South Abington Township, PA and Benton Harbor, MI, on the one hand, and, on the other, points in the United States (except Alaska and Hawaii). RESTRICTIONS: The service authorized in (1) and (2) is restricted to operations in interstate and foreign commerce. The service authorized in (3) is restricted to operations in foreign commerce only and is further restricted to the transportation of traffic having a prior or subsequent movement by water. Said operations are limited to a transportation service to be performed under a continuing contract or contracts, with Sandvik, Inc. Transferee presently holds no authority from this Commission. Application

has not been filed for temporary authority under Section 210a(b).

H. G. HOMME, Jr.,
Secretary.

[FR Doc. 78-35676 Filed 12-21-78; 8:45 am]

[7035-01-M]

[Notice No. 233]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

DECEMBER 13, 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.

NOTE.—All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

MOTOR CARRIERS OF PROPERTY

MC 8771 (Sub-43TA), filed November 1, 1978. Applicant: SAW MILL SUPPLY, INC., 1018 Saw Mill River Road, Yonkers, NY 10701. Representative: John R. Sims, Jr., 915 Pennsylvania Building, 425-13th Street, NW, Washington, DC 20004. *Construction materials and supplies* which, because of their size, or weight, require the use

of special equipment, from Conklin, NY to Monroe, MI, and Kermit, WV, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Cives Steel Company, New York Division, P.O. Box K, Shaw Road, Conklin, NY 13748. SEND PROTESTS TO: Maria B. Kejss, ICC, 26 Federal Plaza, New York, NY 10007.

MC 41432 (Sub-158TA), filed October 31, 1978. Applicant: EAST TEXAS MOTOR FREIGHT LINES, INC., P.O. Box 10125, 2355 Stemmons Freeway, Dallas, TX 75207. Representative: Eldon E. Bresee (same as above). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities*, except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment. (1) Between San Antonio, TX and Del Rio, TX serving the intermediate point of Hondo, TX: From San Antonio over U.S. Hwy 90 to Del Rio and return over the same route. (2) Between San Antonio, TX and Eagle Pass, TX: From San Antonio over U.S. Hwy 81 to junction U.S. Hwy 57, then over U.S. Hwy 57 to Eagle Pass and return over the same route. (3) Between Uvalde, TX and Carrizo Springs, TX, serving Uvalde, La Pryor and Carrizo Springs for purposes of joinder only: From Uvalde over U.S. Hwy 83 to Carrizo Springs and return over the same route. (4) Between Fort Stockton, TX and Laredo, TX serving the intermediate points of Del Rio and Eagle Pass, TX: From Fort Stockton over U.S. Hwy 285 to junction U.S. Hwy 90, then over U.S. Hwy 90 to junction U.S. Hwy 277, then over U.S. Hwy 277 to junction U.S. Hwy 83, then over U.S. Hwy 83 to Laredo, and return over the same route. (5) Between junction U.S. Hwy 81 and U.S. Hwy 57 and Laredo, TX, serving the junction of U.S. Hwy 81 and U.S. Hwy 57 for purposes of joinder only: From junction U.S. Hwy 81 and U.S. Hwy 57 over U.S. Hwy 81 to Laredo, and return over the same route. (6) Between San Marcos, TX and Corpus Christi, TX, serving the intermediate points of Seguin, Beeville and Portland, TX: From San Marcos over TX Hwy 123 to junction U.S. Hwy 181, then over U.S. Hwy 181 to Corpus Christi and return over the same route. (7) Between San Antonio, TX and junction U.S. Hwy 181 and TX Hwy 123, serving junction U.S. Hwy 181 and TX Hwy 123 for purposes of joinder only: From San Antonio over U.S. Hwy 181 to junction TX Hwy 123 and return over the same route. (8) Between San Antonio, TX and Port Lavaca, TX serving the intermediate points of Cuero and Victoria, TX: From San Antonio over U.S. Hwy 87 to Port Lavaca and return over the same

route. (9) Between junction U.S. Hwy 90 and U.S. Hwy 77 and junction U.S. Hwy 77 and alternate U.S. Hwy 77 serving the intermediate points of Hallettsville, Yoakum and Cuero, TX and serving junctions for purposes of joinder only: From junction U.S. Hwy 90 and U.S. Hwy 77 over U.S. Hwy 77 to junction alternate U.S. Hwy 77, then over alternate U.S. Hwy 77 to junction U.S. Hwy 77 and return over the same route. (10) Between San Marcos, TX and junction alternate U.S. Hwy 90 and alternate U.S. Hwy 77, serving the intermediate point of Shiner, TX: From San Marcos over TX Hwy 80 to Luling, then over U.S. Hwy 183 to junction alternate U.S. Hwy 90, then over alternate U.S. Hwy 90 to junction alternate U.S. Hwy 77 and return over the same route. (11) Between junction alternate U.S. Hwy 90 and U.S. Hwy 183 and Cuero, serving junction of alternate U.S. Hwy 90 and U.S. Hwy 183 for purposes of joinder only: From junction alternate U.S. Hwy 90 and U.S. Hwy 183 over U.S. Hwy 183 to Cuero and return over the same route. (12) Between Corpus Christi and junction U.S. Hwy 44 and TX Hwy 83, serving the intermediate points of Robstown and Alice, TX and serving junction U.S. Hwy 44 and TX Hwy 83 for purposes of joinder only: From Corpus Christi over TX Hwy 44 to junction U.S. Hwy 59, then over TX Hwy 44 to junction U.S. Hwy 83 and return over the same route. (13) Between Houston, TX and Laredo, TX, serving the intermediate points of Victoria and Beeville, TX: From Houston over U.S. Hwy 59 to Laredo and return over the same route. (14) Between Houston, TX and Freeport, TX serving the intermediate point of Clute, TX: From Houston over TX Hwy 288 to Freeport and return over the same route. (15) Between Galveston, TX and Freeport, TX: From Galveston over U.S. Hwy 75 to junction TX Hwy 6, then over TX Hwy 6 to junction TX F.M. Hwy 2004, then over TX F.M. Hwy 2004 to junction TX Hwy 288, then over TX Hwy 288 to Freeport and return over the same route. (16) Between Angleton, TX and Corpus Christi, TX serving the intermediate points of Bay City, Point Comfort, Port Lavaca, Aransas Pass, Gregory and Portland, TX and the off-route points of Sweeny, Seadrift and Ingleside, TX and serving Angleton for purposes of joinder only: From Angleton over TX Hwy 35 to junction U.S. Hwy 181, then over U.S. Hwy 181 to Corpus Christi and return over the same route. (17) Between Wharton, TX and Bay City, TX, serving Wharton for the purpose of joinder only: From Wharton over TX Hwy 60 to Bay City and return over the same route. (18) Between junction U.S. Hwy 59 and TX Hwy 111 and junction TX Hwy 71 and

TX Hwy 35, serving junctions for purposes of joinder only: From junction U.S. Hwy 59 and TX Hwy 111 over TX Hwy 111 to junction TX Hwy 111 and TX Hwy 71, then over TX Hwy 71 to junction TX Hwy 71 and TX Hwy 35 and return over the same route. (19) Between Corpus Christi, TX and junction TX Hwy 9 and U.S. Hwy 281, serving junction TX Hwy 9 and U.S. Hwy 281 for purposes of joinder only: From Corpus Christi over TX Hwy 9 to junction U.S. Hwy 281 and return over the same route. (20) Between Hallettsville, TX and Victoria, TX: From Hallettsville over U.S. Hwy 77 to Victoria and return over the same route. (21) Between San Antonio, TX and McAllen, TX serving the intermediate points of Pleasanton and Alice, TX: From San Antonio over U.S. Hwy 281 to McAllen and return over the same route. (22) Between Victoria, TX and Brownsville, TX, serving the intermediate points of Robstown, Bishop and Kingsville, TX: From Victoria over U.S. Hwy 77 to Brownsville and return over the same route. (23) Between Laredo, TX and Harlingen, TX: From Laredo over U.S. Hwy 83 to Harlingen and return over the same route. (24) Serving all intermediate and off-route points in Hidalgo, Willacy and Cameron Counties in connection with the routes set forth in 21, 22, and 23 above. (25) Between Jacksonville, FL and Beaumont, TX: From Jacksonville over I-10 to Beaumont and return over the same route. (26) Between Jacksonville, FL and Beaumont, TX: From Jacksonville over I-10 to junction I-12, then over I-12 to junction I-10, then over I-10 to Beaumont and return over the same route. (27) Between Atlanta, GA and junction I-65 and I-10 serving junction I-65 and I-10 for purposes of joinder only: From Atlanta over I-85 to junction I-65, then over I-65 to junction I-10 and return over the same route, and (28) Between Birmingham, AL and junction I-10 and U.S. Hwy 11, serving junction I-10 and U.S. Hwy 11 for purposes of joinder only: From Birmingham over U.S. Hwy 11 to junction I-10 and return over the same route, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): There are (509) statements of 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: Opal M. Jones, ICC, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 48958 (Sub-164TA), filed November 1, 1978. Applicant: ILLINOIS-CALIFORNIA EXPRESS, INC., 510 East 51st Avenue, Denver, CO 80216. Representative: Lee E. Lucero (same as above). *Articles dealt in by whole-*

sale or retail drug, grocery and department stores, from the facilities of Warner-Lambert Co., at or near Elk Grove Village and Rockford, IL, to the facilities of Warner-Lambert Co., at or near Anaheim, CA, for 180 days. Applicant does not intend to tack the authority with any other held by it. Supporting shipper(s): Warner-Lambert Co., 201 Tabor Road, Morris Plains, NJ 07950. Send protests to: Roger L. Buchanan, ICC, 492 U.S. Customs House, Denver, CO 80202.

MC 51146 (Sub-666TA), filed December 1, 1978. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. *Metal containers*, from the facilities of Cleveland Container Corporation at or near Omaha, NE, to points in CO, IL, IN, IA, KS, MN, MO, MT, NM, OK, TX, UT, WI, and WY, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days operating authority. Supporting shipper(s): Cleveland Container Corporation, 1801 N. 11th Street, Omaha, NE 68110 (Gerald W. Heinen). Send protests to: Gail Daugherty, ICC, U.S. Federal Building and Courthouse, 517 E. Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 53841 (Sub-18TA), filed October 17, 1978. Applicant: W. H. CHRISTIE & SONS, Box 517, East State Street, Knox, PA 16232. Representative: John A. Pillar, esq., 205 Ross Street, Pittsburgh, PA 15219. *Pillows, pads, and paddings*, from the facilities of Chemical Specialties Division—Hoover Universal, Inc. at or near Farwell, MI to Jersey City, NJ, Chicago, IL and Rocky Mount, NC. Supporting shipper(s): Chemical Specialties Division—Hoover Universal, Inc., Route 2, Triport Road, Georgetown, KY 40324. Send protests to: John England, District Supervisor, I.C.C., 2111 New Federal Building, Pittsburgh, PA 15222.

MC 69833 (Sub-138TA), filed October 31, 1978. Applicant: ASSOCIATED TRUCK LINES, INC., 200 Monroe Ave., NW-6th Floor, Grand Rapids, MI 49503. Representative: Harry Pohlad (same address as applicant). Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting general commodities (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between Greenup, IL and Terre Haute, IN over U.S. Hwy 40 (also Interstate Hwy 70) in connection with carrier's authorized regular route operations, serving no intermediate points and serving the terminal for purpose of joinder only, for 180 days.

Supporting shipper(s): None. Send protests to: C. R. Flemming, ICC, 225 Federal Building, Lansing, MI 48933.

MC 69834 (Sub-17TA), filed November 1, 1978. Applicant: PRICE TRUCK LINE, INC., 2945 North Market, Wichita, KS 67219. Representative: Paul V. Dugan, 2707 West Douglas, Wichita, KS 67213. *Crayons, educational school art and hobby supplies and related commodities, and all items and materials used in manufacturing, packaging, distribution and sale of the above items*, to, from and between Winfield, KS, and Easton, PA, on the one hand, and points and places in KS, on the other, for 180 days. Supporting shipper(s): Binney & Smith, Inc., P.O. Box 431, Easton, PA 18042. Send protests to: M. E. Taylor, ICC, 101 Litwin Building, Wichita, KS 67202.

MC 103051 (Sub-458TA), filed November 1, 1978. Applicant: FLEET TRANSPORT COMPANY, INC., P.O. Box 90408, Nashville, TN 37209. Representative: Russell E. Stone (Same as above). *Inedible tallow*, in bulk, in tank vehicles, from Bessemer, AL to Springfield, TN, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Birmingham Hide and Tallow Co., Inc., P.O. Box 1596, Birmingham, AL 35206. SEND PROTESTS TO: Glenda Kuss, ICC, Suite A-422—U.S. Court House, 801 Broadway, Nashville, TN 37203.

MC 107295 (Sub-895TA), filed November 1, 1978. Applicant: PRE-FAB TRANSIT CO., P.O. Box 146, Farmer City, IL 61842. Representative: Duane Zehr (Same as above). *Materials, equipment and supplies* (except commodities in bulk), used in the manufacture and distribution of roofing, roofing materials, and siding, from points in AL, AR, FL, GA, IL, IN, IA, KS, KY, LA, MS, MO, NC, OH, OK, SC, TN, TX, VA and WV, to Meridian, MS, and Little Rock, AR, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Masonite Corporation, Roofing Division, P.O. Box 577, Valley Road, Meridian, MS 39301. SEND PROTESTS TO: Charles D. Little, ICC, 414 Leland Office Building, 527 E. Capitol Avenue, Springfield, IL 62701.

MC 107403 (Sub-1129TA), filed October 30, 1978. Applicant: MATLACK, INC., 10 W. Baltimore Ave., Lansdowne, Pa. 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). *Cement*, in bags, from Ravenna, N.Y., to Oak Harbor, Ohio, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Atlantic Cement Co., Inc., P.O. Box 30, Stamford, Conn. 06904. SEND PROTESTS TO: T. M. Espósito, ICC, 600 Arch St., Room 3238, Philadelphia, Pa. 19106.

MC 108117 (Sub-8TA), filed November 1, 1978. Applicant: WILLIAM H. PATTERSON, JR., d.b.a. PATTERSON TRUCKING, 46 Waln Avenue, Yardville, NJ 08620. Representative: Denis James Lawler, 37 South 20th Street, Philadelphia, PA 19103. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: *Sulphate*, from Bethlehem, PA to Yardville, NJ, under a continuing contract or contracts with Agway, Inc., Fertilizer Division, for 180 days. SUPPORTING SHIPPER(S): Agway, Inc., Fertilizer Division, Box 4933, Syracuse, NY 13221. SEND PROTESTS TO: John P. Lynn, ICC, 428 East State Street, Room 204, Trenton, NJ 08608.

MC 108207 (Sub-487TA), filed November 1, 1978. Applicant: FROZEN FOOD EXPRESS, INC., 318 Cadiz Street (P.O. Box 225888), Dallas, TX 75265. Representative: M. W. Smith (Same as above). *Foodstuffs* (except commodities in bulk), between New Orleans, LA on the one hand, and, on the other, points in TX, for 180 days. SUPPORTING SHIPPER(S): Hunt-Wesson Foods, P.O. Box 61770, New Orleans, LA 70161. SEND PROTESTS TO: Opal M. Jones, ICC, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 110328 (Sub-14TA), filed November 1, 1978. Applicant: ROY A. LIEPHART TRUCKING, INC., 1298 Toronita Street, York, PA 17402. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. *Foodstuffs*, between the plantsite storage facilities of Knouse Foods, Inc., at or near Peach Glen and Orrtanna, PA, on the one hand, and, on the other, Baltimore, MD and its commercial zone, for 180 days. Restricted to traffic having a prior or subsequent movement by water or rail. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Knouse Foods, Inc., Peach Glen, PA 17306. SEND PROTESTS TO: Charles F. Myers, ICC, P.O. Box 869 Federal Square Station, Harrisburg, PA 17108.

MC 110563 (Sub-248TA), filed November 1, 1978. Applicant: COLDWAY FOOD EXPRESS, INC., P.O. Box 747, State Route 29 North, Sidney, OH 45365. Representative: John L. Maurer (Same as above). *Candy, chocolate coating, chocolate drops, cocoa powder, and solid and broken chocolate*, from the facilities of Ward Chocolate Company, located at or near Philadelphia, PA and Pennsauken, NJ to Denver, CO, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Ward Chocolate Co., Margaret and James St., Philadelphia, PA 19137. SEND PROTESTS TO: ICC, 313 Fed-

eral Office Building, 234 Summit Street, Toledo, OH 43604.

MC 111401 (Sub-534TA), filed November 1, 1978. Applicant: GROEN-DYKE TRANSPORT, INC., 2510 Rock Island Boulevard, P.O. Box 632, Enid, OK 73701. Representative: Victor R. Comstock (Same as above). *Liquid waste (for disposal)*, in bulk, in tank vehicles, from Boulder, CO to Grandview, ID, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Arapahoe Chemicals, Inc., 2075 N. 55th Street, Boulder, CO 80301. SEND PROTESTS TO: Connie Stanley, ICC, Room 240 Old Post Office and Court House Building, 215 NW. 3rd, Oklahoma City, OK 73102.

MC 112713 (Sub-229TA), filed November 27, 1978. Applicant: YELLOW FREIGHT SYSTEM, INC., P.O. Box 7270, Shawnee Mission, KS 66207. Representative: John M. Records (Same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities* (except Classes A and B explosives, commodities in bulk, household goods as defined by the Commission, commodities of unusual value and those requiring special equipment), serving the facilities of Continental Oil Company, Conquista Project near Falls City, TX, as an off-route point in connection with carrier's otherwise authorized operations, for 180 days. SUPPORTING SHIPPER: Continental Oil Company, Conquista Project, P.O. Box 309, Falls City, TX 78113. SEND PROTESTS TO: John V. Barry, ICC, 911 Walnut St., Rm. 600, Kansas City, MO 64106.

MC 113466 (Sub-8TA), filed November 1, 1978. Applicant: CECIL E. AND ROBERT A. ALTO, dba ALTO BROS. TRUCKING, Route 1, Box 266 D, Eureka, CA 95501. Representative: Earle V. White, 2400 SW. 4th Avenue, Portland, OR 97201. *Lumber* (including plywood), *flakeboard*, and *wood pulp*, from points in Del Norte, Siskiyou, Trinity, Humboldt, and Mendocino Counties, CA to points in Sonoma, Shasta, and Tehama Counties, CA, for subsequent out-of-state movements by railroad, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Simpson Timber Company, P.O. Drawer V, Arcata, CA 95521. Louisiana-Pacific Corporation, P.O. Box 158, Samoa, CA 95564. SEND PROTESTS TO: A. J. Rodriguez, ICC, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 114457 (Sub-440TA), filed October 17, 1978. Applicant: DART TRANSIT COMPANY, 2102 University Avenue, St. Paul, MN 55114. Representative: James H. Wills, 2102 Univer-

sity Avenue, St. Paul, MN 55114. *Adhesive cement*, *tackless strips*, *carpet accessories*, *advertising material* and *materials, equipment, and supplies* used in the installation thereof (ECIB) from the plantsite and warehouse facilities of Taylor Industries, Inc. at or near Conyer, GA to points in ME, VT, NH, MA, CT, RI, NY, PA, NJ, PA, NY, MD, DE, WV, DC, VA, KY, TN, NC, SC and FL, for 180 days. SUPPORTING SHIPPER(S): Taylor Industries, 900 Rockdale Industrial Boulevard, Conyers, GA 30207. SEND PROTESTS TO: Delores A. Poe, Transportation Assistant, ICC, 414 Federal Building & U.S. Courthouse, 110 South 4th Street, Minneapolis, MN 55401.

MC 114457 (Sub-443TA), filed October 17, 1978. Applicant: DART TRANSIT COMPANY, 2102 University Avenue, St. Paul, MN 55114. Representative: James H. Wills, 2102 University Avenue, St. Paul, MN 55114. *Newsprint* and *groundwood paper* from the facilities of Bowater Southern Paper Corporation, at or near Calhoun, TN to points in KY, for 180 days. SUPPORTING SHIPPER(S): Bowater Southern Paper Corporation, Calhoun, TN 37309. SEND PROTESTS TO: Delores A. Poe, Transportation Assistant, ICC, 414 Federal Building, U.S. Courthouse, 110 South 4th Street, Minneapolis, MN 55401.

MC 115233 (Sub-5TA), filed October 30, 1978. Applicant: MARSHALL STORAGE COMPANY, Highway 19 East, P.O. Box 145, Marshall, Minn 56258. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, N. Dak. 58108. *Canned foodstuffs*, from the facilities of Big Stone, Inc., located at or near Arlington and Ortonville, Minn and Bloomer, Ws., to points in Arkansas, Illinois, Iowa, Kansas and Missouri, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Big Stone, Inc., P.O. Box 86, Chaska, MN 55318. SEND PROTESTS TO: Delores A. Poe, ICC, 414 Federal Building and U.S. Court House, 110 South 4th Street, Minneapolis, Minn. 55401.

MC 115826 (Sub-357TA), filed October 17, 1978. Applicant: W.J. DIGBY, INC., 1960 31st Street, P.O. Box 5088, Terminal Annex, Denver, CO 80217. Representative: Howard Gore, 6015 East 58th Avenue, Commerce City, CO 80022. *Foodstuffs*, while moving in trailers equipped with mechanical refrigeration units, from Kansas City, KS, Kansas City, MO, and their respective commercial zones to points in AL, AR, AZ, CT, FL, GA, KY, LA, MA, MD, ME, MS, NC, NH, NJ, NM, NY, OK, PA, RI, SC, TN, TX, VA, VT, and WV, for 180 days. SUPPORTING SHIPPER(S): Commercial Distribution Centre, Inc., P.O. Box 477, Inde-

pendence, MO 64051. SEND PROTESTS TO: Herbert C. Ruoff, District Supervisor, ICC, 492 U.S. Customs House, 721 19th Street, Denver, Colorado 80202.

MC 116947 (Sub-62TA), filed October 30, 1978. Applicant: SCOTT TRANSFER CO., INC., 920 Ashby Street SW., Atlanta, GA 30310. Representative: William Addams, Suite 212, 5299 Roswell Road NE., Atlanta, GA 30342. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Steel cans*, *can ends*, from Rockford, IL to Pascagoula, MS, under a continuing contract or contracts with National Can Corporation, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): National Can Corporation, 8101 West Higgins Road, Chicago, IL 60631. SEND PROTESTS TO: Sara K. Davis, ICC, 1252 W. Peachtree Street NW., Room 300, Atlanta, GA 30309.

MC 117589 (Sub-54TA), filed November 22, 1978. Applicant: PROVISIONERS FROZEN EXPRESS, INC., 3801 7th Avenue South, Seattle, WA 98108. Representative: Michael D. Duppenhaller, 211 South Washington Street, Seattle, WA 98104. *Canned food products*, *when moving in mixed loads with frozen fruits*, *frozen berries*, *frozen vegetables*, *frozen potatoes* and *frozen potato products* or *frozen seafood*, from points in WA, OR and ID to Denver and Pueblo, CO and Salt Lake City, UT for 180 days. SUPPORTING SHIPPERS: Stein Foods, 115 East 4th Street, Pueblo, Colo. 81002 United Food Service, Inc., 3770 East 40th Avenue, Denver, Colo. 80250. Swiftsure Fisheries, 200 West Thomas, Seattle, Wash. 98119. East Point Seafoods, South Bend, Wash. SEND PROTESTS TO: Shirley M. Holmes, ICC, 858 Federal Bldg., Seattle, Wash. 98174.

MC 117664 (Sub-12TA), filed November 1, 1978. Applicant: DENTON TRUCKING, INC., P.O. Box 33, Denton, MD 21629. Representative: Chester A. Zyblut, 366 Executive Building, Washington, D.C. 20005. *Lime*, in bulk, in dump vehicles, from the facilities of J. E. Baker Lime Co., York, PA to Seaford, DE, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Soll Service, Inc., P.O. Box 570, Seaford, DE 19973. SEND PROTESTS TO: William L. Hughes, ICC, 1025 Federal Building, Baltimore, MD 21201.

MC 117786 (Sub-35TA), filed October 17, 1978. Applicant: RILEY WHIT- TLE, INC., P.O. Box 19038, Phoenix, AZ 85009. Representative: A. Michael Bernstein, 1441 E. Thomas Road, Phoenix, AZ 85014. *Paper and paper products*, from the facilities of The

Miami Valley Paper Shippers' Association, Inc., in Hamilton, OH to points in WA, OR, CA, AZ, NV, ID, MT, WY, UT, CO, NM, KS, OK, TX, AR, MO, LA, MS, AL, GA and TN, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): The Miami Valley Paper Shippers' Association, Inc., 845 East Avenue, Hamilton, OH 45011. Send protests to: Andrew V. Baylor, ICC, Room 2020 Federal Building, 230 N. First Avenue, Phoenix, AZ 85025.

MC 118159 (Sub-295TA), filed October 30, 1978. Applicant: NATIONAL REFRIGERATED TRANSPORT, INC., P.O. Box 51366, Dawson Station, Tulsa, OK 73102. Representative: Warren L. Troupe, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. Containers, container ends and materials and supplies used in the manufacture and distribution of containers, from the facilities of National Can Corporation at Oklahoma City, OK, and Pascagoula, MS, to points in the United States, for 180 days. Applicant has also filed an underlying ETA seeking up to 90 days operating authority. Supporting shipper: National Can Corporation, 8101 W. Higgins Road, Chicago, IL 60631 (Floyd C. Stone). Send protests to: Connie Stanley, ICC, Room 240, Old U.S. Post Office, 215 Northwest Third, Oklahoma City, OK 73102.

MC 119668 (Sub-9TA), filed October 17, 1978. Applicant: FORREST RATLIFF & AUBURN RATLIFF, d.b.a. Ratliff Trucking Service, P.O. Box 366, Oakwood, VA 24631. Representative: Edward G. Villalon, 1032 Pennsylvania Building, Pennsylvania Avenue & 13th Street NW., Washington, D.C. 20004. (1) Mining equipment and machinery and parts and accessories therefor, between the facilities of Jewel Coal & Coke Company, at or near Vansant, VA, Manchester and Whitley City, KY, and Sutton, WV; (2) Refractory materials and fire brick, from Oak Hill, OH, Claysburg, PA, Hotchins, KY, Augusta, GA, and Buffington, IN, to the facilities of Jewel Coal & Coke Company at or near Vansant, VA; and (3) Iron and steel articles, from Bethlehem, PA, and Sparrows Point, MD, to the facilities of Jewel Coal & Coke Company at or near Vansant, VA, for 180 days. Supporting shipper(s): Jewel Coal & Coke Company, P.O. Box 46, Vansant, VA. Send protests to: Paul D. Collins, District Supervisor, Room 10-502 Federal Building, 400 North 8th Street, Richmond, VA 23240.

MC 121568 (Sub-11TA), filed December 1, 1978. Applicant: HUMBOLDT EXPRESS, INC., 345 Hill Avenue, Nashville, Tennessee 37211. Representative: A. Doyle Cloud, Jr., 2008 Clark Tower, 5100 Poplar Avenue,

Memphis, Tennessee 38137. (1) Articles made totally or partially of plastic, and items utilized in the sale or distribution thereof, from the facilities of the Tupperware Company, located at or near Halls, TN, to points in Texas; and (2) Items utilized in the sale, manufacture, or distribution of the commodities in (1) above, from Texas, Louisiana, and Arkansas, to the facilities of the Tupperware Company located at or near Halls, TN, for 180 days. Supporting shipper: Tupperware Company, Div. of Dart Industries, Inc., P.O. Box 751, Woonsocket, RI 02895. Send protests to: Glenda Kuss, ICC, A-422—U.S. Court House, 801 Broadway, Nashville, TN 37221.

MC 124151 (Sub-9TA), filed October 17, 1978. Applicant: VANGUARD TRANSPORTATION, INC., Lafayette Street, Carteret, NJ 07008. Representative: E. Stephen Heisley, Suite 805, 666 Eleventh Street NW., Washington, D.C. 20001. Liquid chemicals, in bulk, in tank vehicles, from Philadelphia, PA, and its commercial zone to New York, NY, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Rohm & Haas, Independence Mall West, Philadelphia, PA 19105. Send protests to: Robert E. Johnston, District Supervisor, ICC, 9 Clinton Street, Newark, NJ 07102.

MC 124211 (Sub-344TA), filed November 1, 1978. Applicant: HILT TRUCK LINE, INC., P.O. Box 988 DTS, Omaha, NE 68101. Representative: Thomas L. Hilt (same as above). Foods and foodstuffs (except frozen foods, meats, and packinghouse products as defined by the Commission), food ingredients, drugs, vitamins, toilet preparations, food grinders, water purifiers, can openers, container lids, cookbooks, seed sprouting kits, safety matches, candles, and seeds, and commodities used in the manufacture, distribution, and sale of the aforementioned commodities (except in bulk, in tank or hopper type vehicles), from the facilities of Arrowhead Mills, Inc., located at Hereford, TX and Clovis, NM to points in FL, NC, MD, MI, IL, PA, NJ, NY, MA, CT and TN, for 180 days. Supporting shipper(s): Arrowhead Mills, Inc., P.O. Box 866, Hereford, TX 79045. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th Street, Omaha, NE 68102.

MC 126196 (Sub-14TA), filed November 1, 1978. Applicant: BLACHOWSKE TRUCK LINE, INC., Rural Route 1, Fairmont, MN, 56031. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. Coal, from points in Custer, Rosebud and Treasure Counties, MT; Bowman, McHenry, McLean and Mercer Counties, ND and Campbell Crook, Johnson, Sheridan and Weston Counties,

WY to points in IA on and north of U.S. Highway 20, MN south of U.S. Highway 12 and Campbell County, SD; and from St. Paul and Newport, MN to points in MN south of U.S. Highway 12 and IA on and north of U.S. Highway 20, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS(S): The Pillsbury Company, 608 Second Avenue South, Minneapolis, MN 55402. Blachowske Grain and Feed, Route 1, Box 233, Fairmont, MN 56031. SEND PROTESTS TO: Delores A. Poe, ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 126844 (Sub-58TA), filed October 17, 1978. Applicant: R.D.S. TRUCKING CO., INC., 1713 North Main Road, Vineland, NJ 08360. Representative: Terrence D. Jones, 2033 K Street, NW, Washington, D.C. 20006. Frozen foods, from the facilities of Stouffer Foods Corporation at Cleveland and Solon, OH to points in ME, VT, NH, RI, MA, CT, NY, PA, NJ, DE, MD, OH, VA and DC, restricted to the transportation of traffic originating at the named origins, for 180 days. SUPPORTING SHIPPER(S): Stouffer Foods Corporation, 5750 Harper Road, Solon, Ohio 44139. SEND PROTESTS TO: John P. Lynn, Transportation Specialist, ICC, 428 East State Street, Room 204, Trenton, NJ 08608.

MC 127478 (Sub-10TA), filed November 1, 1978. Applicant: WILLIAM M. HAYES, d.b.a. HAYES TRUCKING CO., P.O. Box 31, Winterville, GA 30683. Representative: Virgil H. Smith, Suite 12, 1587 Phoenix Boulevard, Atlanta, GA 30349. Candy and confectionery items, dessert preparations, gumball machines and stands, and advertising displays and materials (in mechanically refrigerated vehicles, except in bulk), from the facilities of Leaf Confectionery, Inc., at Chicago, IL to points in AL, FL, GA, NC, SC, TN and VA, for 180 days. Restricted to shipments originating at the facilities of Leaf Confectionery, Inc., at Chicago, IL and destined to the named destinations. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Leaf Confectionery, Inc., 1155 N. Cicero Avenue, Chicago, IL 60651. SEND PROTESTS TO: Sara K. Davis, ICC, 1252 W. Peachtree Street, N.W., Room 300, Atlanta, GA 30309.

MC 128837 (Sub-4TA), filed November 1, 1978. Applicant: TRUCKING SERVICE, INC., P.O. Box 229, Carlinville, IL 62656. Representative: Robert T. Lawley, 300 Reisch Building, Springfield, IL 62701. Steel pipe and tubing, from Staunton, IL to points in GA, IA, KS, KY, LA, MI, MO, MS, NE, NC, ND, OH, OK, PA, SC, SD,

TN, TX, and WI, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Livingston Pipe & Tubing, Inc., P.O. Box 300, Staunton, IL 62088. SEND PROTESTS TO: Charles D. Little, ICC, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62701.

MC 129032 (Sub-59TA), filed October 17, 1978. Applicant: TOM INMAN TRUCKING, INC., 6015 So. 49th West Avenue, Tulsa, OK 74107. Representative: David R. Worthington, 6015 So. 49th West Avenue, Tulsa, OK 74107. *Fresh and frozen meat products in boxes (except hides and commodities in bulk, in tank vehicles), from the facilities of Packerland Packing Company, Inc., at Green Bay, WI to the State of CA, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Packerland Packing Co., Inc., P.O. Box 1184, Green Bwy, WI 54305. SEND PROTESTS TO: Connie Stanley, Transportation Assistant, Room 240, Old Post Office & Courthouse Building, 215 N.W. 3rd, Oklahoma City, OK 73102.*

MC 134235 (Sub-12TA), filed November 20, 1978. KUHNLE BROTHERS, INC., 15625 Chillicothe Road, P.O. Box 128, Chagrin Falls, OH 44022. Representative: Kenneth T. Johnson, Ronald W. Malin, Bankers Trust Building, Jamestown, NY 14701. *Unit construction drainage systems and parts and components therefor, in flat bed trailers, from the plant site of Aco Drain, Incorporated at or near Chardon, OH to points in MI, WI, IL, MO, IN, PA, NY, WV, VA, KY, TN, MS, AL, GA, NC, SC and FL, for 180 days. SUPPORTING SHIPPER: Aco Drain, Incorporated, 29525 Chagrin Blvd., Cleveland, OH. SEND PROTESTS TO: ICC, 731 Federal Building, 1240 East 9th Street, Cleveland, OH 44199.*

MC 134235 (Sub-12TA), filed November 20, 1978. Applicant: KUHNLE BROTHERS, INC., 15625 Chillicothe Road, P.O. Box 128, Chagrin Falls, OH 44022. Representative: Kenneth T. Johnson, Ronald W. Malin, Bankers Trust Building, Jamestown, NY 14701. *Unit construction drainage systems and parts and components therefor, in flat bed trailers, from the plant site of Aco Drain, Incorporated at or near Chardon, OH to points in MI, WI, IL, MO, IN, PA, NY, WV, VA, KY, TN, MS, AL, GA, NC, SC and FL, for 180 days. Supporting Shipper: Aco Drain, Incorporated, 29525 Chagrin Blvd., Cleveland, OH. Send protests to: ICC, 731 Federal Building, 1240 East 9th Street, Cleveland, OH 44199.*

MC 134477 (Sub-285TA), filed November 1, 1978. Applicant: SCHANNO TRANSPORTATION, INC., 5 West Mendota Road, West St. Paul, MN 55118. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN

55118. *Matches and woodenware, from Cloquet, MN to Dayton, OH, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Diamond International Corp., 733 Third Avenue, New York, NY 10017. SEND PROTESTS TO: Delores A. Poe, ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.*

MC 136228 (Sub-35TA), filed October 17, 1978. Applicant: LUISI TRUCK LINES, INC., P.O. Box H, Milton-Freewater, Ore. 97862. Representative: Philip G. Skofstad, P.O. Box 594, 1300 N.E. Linden, Gresham, Ore. 97030. *Frozen fruits and vegetables, between Weston, Ore. and Walla Walla, Wash., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Jones-Normel Foods, Inc., P.O. Box 68, Weston, Ore. 97886. SEND PROTESTS TO: R. V. Dubay, ICC, 114 Pioneer Courthouse, Portland, Ore. 97204.*

MC 136511 (Sub-29TA), filed November 22, 1978. Applicant: VIRGINIA APPALACHIAN LUMBER CORPORATION, 9640 Timberlake Road, Lynchburg, VA 24502. Representative: Elizabeth A. Purcell, 805 McLachlen Bank Bldg., 666 11th Street, NW, Washington, DC 20001. *New furniture, from Waynesboro, VA to points in AZ, CA, NV, TX, OK; Denver, CO and Salt Lake City, UT, for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: John J. Virag, President, Interlock Furniture Industries of Va., Inc., P.O. Box 2206, Waynesboro, VA 22980; Donn Flem, Traffic Manager, Breuners, 3201 Fostoria, San Ramon, CA 94583. Send protests to: Paul D. Collins, ICC, 10-502 Federal Bldg., 400 N. 8th St., Richmond, VA 23240.*

MC 136605 (Sub-81TA), filed November 29, 1978. Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). *Poly coated iron and steel articles, from the facilities of Simcote, Inc., located at or near St. Paul, MN, to points in the United States in and west of ND, SD, NE, KS, OK, and TK (except AK & HI), for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Simcote, Inc., P.O. Box 97, Newport, MN 55055. SEND PROTESTS TO: Paul J. Labane, ICC, 2602 First Avenue North, Billings, MT 59101.*

MC 136635 (Sub-12TA), filed November 1, 1978. Applicant: UNIVERSAL CARTAGE, INC., 640 W. Ireland Road, South Bend, IN 46614. Representative: Donald W. Smith, P.O. Box 40659, Indianapolis, IN 46240. *Automotive parts, (1) from points in OH, WI, Lower Peninsula of MI, PA; East Hartford, CT; Saco, ME, and St. Louis,*

MO, to the facilities of A. M. General Corporation at South Bend, IN. (2) from the facilities of A. M. General at South Bend, IN, to Rockford, IL, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): A. M. General Corporation, 701 West Chippewa Avenue, South Bend, IN 46614. SEND PROTESTS TO: J. H. Gray, ICC, 343 West Wayne Street, Suite 113, Fort Wayne, IN 46802.

MC 136782 (Sub-6TA), filed November 1, 1978. Applicant: R.A.N. TRUCKING COMPANY, P.O. Box 367, Wheatland, PA 16161. Representative: Warren W. Wallin, 10 S. LaSalle Street, Suite 1600, Chicago, IL 60603. *Meat, meat products, and meat by-products as described in Appendix I to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209 and 766, (except commodities in bulk), from the facilities of Dinner Bell Meats, Inc., at Cleveland, OH, and the facilities of Dinner Bell Foods, Inc., at Defiance and Troy, OH to Windsor Locks, CT and points in the NY, NY Commercial Zone, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Dinner Bell Foods, Inc., P. O. Box 388, Defiance OH 43512. Dinner Bell Meats, Inc., 2699 E. 51st Street, Cleveland, OH. SEND PROTESTS TO: John J. England, ICC, 1000 Liberty Avenue, 2111 Federal Building, Pittsburgh, PA 15222.*

MC 138676 (Sub-10TA), filed November 13, 1978. Applicant: O-J TRANSPORT COMPANY, 10290 Gratiot, Detroit, Michigan. Representative: Robert E. McFarland, McFarland & Bullard, 999 West Big Beaver Road, Suite 1002, Troy, Michigan 48064. *General commodities (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) between Midland, MI, on the one hand, and, on the other, points in IL; IN; WI; that part of IA on and east of a line beginning at the IA-MO border and extending north along Hwy I-35 to the IA-MN border; and that part of MN on, east, and south of a line beginning at the IA-MN border and extending north along Hwy I-35 to its intersection with Hwy I-35W, north along Hwy I-35W to its intersection with Hwy I-494, west and north along I-494 to its intersection with Hwy I-694, east and south along Hwy I-694 to its intersection with I-94, and east along I-94 to the WI-MN border, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS: There are approximately (5) statements of support which may be examined at the field office named below. SEND PROTESTS TO: Timo-*

thy S. Quinn, ICC, 604 Federal Building & U.S. Courthouse, 231 W. Lafayette Blvd., Detroit, Mich. 48226.

MC 138882 (Sub-169TA), filed October 17, 1978. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, Ala. 36081. Representative: George A. Olsen, P.O. Box 357, Gladstone, N.J. 07934. *Lumber and lumber mill products*, from points in California to points in Kentucky, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Steel City Lumber Company, 3100 Lorna Road, Birmingham, Ala. 35216. SEND PROTESTS TO: Mabel E. Holston, ICC, room 1616-2121 Building, Birmingham, Ala. 35203.

MC 139482 (Sub-71TA), filed October 26, 1978. Applicant: NEW ULM FREIGHT LINES, INC., P. O. Box 877, New Ulm, Minn. 56073. Representative: James E. Ballenthin, 630 Osborn Building, St. Paul, Minn. 55102. *Foodstuffs* (in vehicles equipped with mechanical refrigeration) from the plantsites of Hershey Chocolate Company and H. B. Reese Company located in Derry Township, Dauphin County, Pa. and Y & S Candies, Inc. located in E. Hempfield Township, Lancaster County, Pa., to points in Mich., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Hershey Chocolate Company, 19 East Chocolate Avenue, Hershey, Pa. 17033. SEND PROTESTS TO: Delores A. Poe, ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, Minn. 55401.

MC 139485 (Sub-12TA), filed November 1, 1978. Applicant: TRANS CONTINENTAL CARRIERS, INC., 169 East Liberty Avenue, Anaheim, CA 92803. Representative: David P. Christianson, 707 Wilshire Boulevard, Suite 1800, Los Angeles, CA 90017. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Building materials*, between Medina County and Cuyahoga County, OH; MD; and PA, on the one hand, and, on the other, points in the United States, under a continuing contract or contracts with Donn Products, Inc., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Donn Products, Inc., 1000 Crocker Road, Westlake, OH 44145. SEND PROTESTS TO: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 139485 (Sub-13TA), filed November 1, 1978. Applicant: TRANS CONTINENTAL CARRIERS, INC., 169 East Liberty Avenue, Anaheim, CA 92803. Representative: David P. Christianson, 707 Wilshire Boulevard, Suite

1800, Los Angeles, CA 90017. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Polyester body filler, polishing and cleaning compounds, tools, parts and accessories, buffing pads, cleaning cloths, putty and paint*, from Stark County, OH, to IN, IL, WI, MN, IA, MO, AR, LA, TX, OK, KS, NE, SD, ND, MT, WY, AZ, UT, ID, NV, WA, OR, NM, CO and CA, under a continuing contract or contracts with U.S. Chemical & Plastics Company, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): U.S. Chemical & Plastics Company, 1446 Tuscarawas West Street, Canton, OH 44706. Send protests to: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 139485 (Sub-14TA), filed November 1, 1978. Applicant: TRANS CONTINENTAL CARRIERS, INC., 169 East Liberty Avenue, Anaheim, CA 92803. Representative: David P. Christianson, 707 Wilshire Boulevard, Suite 1800, Los Angeles, CA 90017. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Paint, paint additives and paint accessories*, from Cuyahoga County, OH, and Queens County, NY, to points in the United States, under a continuing contract or contracts with Limbacher Paint & Color Works, Inc., for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Limbacher Paint & Color Works, Inc., 13000 Athens Avenue, Lakewood, OH 44107. Send protests to: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 140086 (Sub-1TA), filed October 11, 1978. Applicant: De LARIA TRANSPORT, INC., 327 8th Avenue N.W., New Brighton, MN 55112. Representative: Bruce A. Rasmussen, 1110 Northwestern Bank Building, Minneapolis, MN 55402. *Crude coffee oil*, in bulk, in tank vehicles, from Gonvick, MN, to Ripon, CA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper: Northern Sun Products Co., P.O. Box 646, Gonvick, MN 56644. Send protests to: Delores A. Poe, ICC, 414 Federal Building, 110 South 4th Street, U.S. Court House, Minneapolis, MN 55401.

MC 142508 (Sub-39TA), filed November 1, 1978. Applicant: NATIONAL TRANSPORTATION, INC., P.O. Box 37465, 10810 South 144th Street, Omaha, NE 68137. Representative: Lanny N. Fauss, P.O. Box 37096, Omaha, NE 68137. *Such commodities as are used or dealt in by manufacturers of motor vehicle parts and supplies* (except commodities in bulk), from points in MI and OH to the facilities

of Standard Motor Products, Inc., at Long Island City, NY, for 180 days. Supporting shipper(s): Standard Motor Products, Inc., 27-18 Northern Boulevard, Long Island City, NY 11101. Send protests to: Carroll Russell, ICC, Suite 620, 110 No. 14th Street, Omaha, NE 68102.

MC 142686 (Sub-10TA), filed November 1, 1978. Applicant: MID-WESTERN TRANSPORT, INC., 10506 South Shoemaker, Santa Fe Springs, CA 90670. Representative: Joseph Fazio (same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Air conditioning equipment, and materials and supplies used in the manufacture, distribution, and installation thereof*, from the facilities of Bohn Heat Transfer Division, Gulf & Western Manufacturing Company at Los Angeles, CA to Akron, Cincinnati, Cleveland and Columbus, OH; Albany, College Park and Dublin, GA; Birmingham, AL; Chicago and National Stockyard, IL; Detroit, MI; East Franklin, NC; Grand Junction, CO; Hill AFB, VT; New York, NY; Newark, NJ; North Miami and Tampa, FL; Philadelphia and Pittsburgh, PA; Springfield, MA; Staunton, VA; St. Louis, MO; and Tyler, TX, under a continuing contract or contracts with Bohn Heat Transfer Division, for 180 days. Supporting shipper(s): Bohn Heat Transfer Division, 1625 East Voordees Street, Danville, IL 61832. Send protests to: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 142909 (Sub-3TA), filed November 28, 1978. Applicant: TIMBER TRUCKING, INC., 4100 South West Temple, Salt Lake City, UT 84107. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. *Laminated beams*, from the facilities of Glu-Laminated Wood Systems, Inc., at or near Magna, UT, to CO, NM, and AZ. Supporting shipper: Glu-Laminated Wood Systems, Inc., 3909 South 800 West, Magna, UT 84044. Send protests to: Lyle D. Helfer, ICC, Room 5301, Federal Building, 125 South State Street, Salt Lake City, UT 84138.

NOTE.—An underlying ETA seeks 90 days authority.

MC 143127 (Sub-17TA), filed November 1, 1978. Applicant: K. J. TRANSPORTATION, INC., 1000 Jefferson Road, P. O. Box 9764, Rochester, NY 14623. Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202. *Empty glass bottles, one gallon or less in capacity*, from the facilities of the National Bottle Co., at or near Vienna, WV to points in KY, NJ, PA and NY, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): National

Bottle Company, 1 Bala Cynwyd Plaza, Bala Cynwyd, PA 19004. SEND PROTESTS TO: ICC, U. S. Courthouse & Federal Building, 100 S. Clinton Street, Room 1259, Syracuse, NY 13260.

MC 143276 (Sub-8TA), filed October 17, 1978. Applicant: WEAVER TRANSPORTATION COMPANY, 5452 Oakdale Road, Smyrna, GA 30080. Representative: Jack Weaver, 5452 Oakdale Road, Smyrna, GA 30080. *Roofing, materials, viz: Roofing material rolls, asphalt roofing, composition shingles and composition roofing, from the plantsite of Johns-Manville Sales Corp., at or near Savannah, Chatham County, GA to all points in TN and NC, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): John-Manville Sales Corp., 3300 Holcomb Bridge Road, Norcross, GA 30092. SEND PROTESTS TO: Sara K. Davis, Transportation Assistant, ICC, 1252 W. Peachtree Street, NW, Room 300, Atlanta, GA 30309.*

MC 144203 (Sub-2TA), filed November 1, 1978. Applicant: HERMAN BROS., INC., 2565 ST. Marys Avenue, P. O. Box 189, Omaha, NE 68101. Representative: Duane L. Stromer (Same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Flour and middlings*, in bulk and packages, from the facilities of ConAgra, Inc., Decatur, AL to points in FL, GA, KY, IL, IN, MS, TN and WV, under a continuing contract with ConAgra, Inc., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): ConAgra, Inc., 200 Kiewit Plaza, Omaha, NE 68131. SEND PROTESTS TO: Carroll Russell, ICC, Suite 620, 110 No. 14th Street, Omaha, NE 68102.

MC 144298 (Sub-4TA), filed October 30, 1978. Applicant: MASTER TRANSPORT SERVICES, INC., 5000 Wyoming Avenue-Suite 203, Dearborn, Mich. 48126. Representative: William B. Elmer, 21635 East Nine Mile Road, St. Clair Shores, Mich. 48080. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Foodstuffs*, in mechanically refrigerated equipment, from Detroit, Mich., to Sarasota and Orlando, Fla., for 180 days. SUPPORTING SHIPPER: Fred Sanders, 100 Oakman Blvd., Detroit, Mich. 48203. SEND PROTESTS TO: Tim Quinn, District Supervisor, ICC, 604 Federal Bldg., and U. S. Courthouse, 231 W. Lafayette Blvd., Detroit, Mich. 48226. Under a continuing contract or contracts with Fred Sanders.

MC 144326 (Sub-5TA), filed November 1, 1978. Applicant: RICHARDSON TRUCKING, INC., 603 8th Street, Greeley, CO 80631. Representative:

William Fred Cantonwine (Same as above). *Animal and poultry feeds*, from Farmland Industries, Inc., Kansas City, KS to points in CO, for 180 days. SUPPORTING SHIPPER(S): Farmland Industries, Inc., P. O. Box 7305, Kansas City, KS 64116. SEND PROTESTS TO: R. L. Buchanan, ICC, 492 U. S. Customs House, 721 9th Street, Denver, CO 80202.

MC 144652 (Sub-1TA), filed November 21, 1978. Applicant: SATELLITE TRANSPORT, INC., P. O. Box 207, Flora, IN 46929. Representative: Robert W. Loser II, 1009 Chamber of Commerce Bldg., Indianapolis, IN 46204. Authority sought to operate as a *Contract carrier*, by motor vehicle, over irregular routes, transporting: *Dry feed and feed ingredients, animal health aids and sanitation products*, between the facilities of Allied Mills, Inc., located at or near Castleton and Ft. Wayne, Indiana on the one hand, and, on the other, points in KY, IL, MI, and OH. RESTRICTION: Restricted to service to be performed under a continuing contract, or contracts with Allied Mills, Inc., for 180 days. Supporting shipper: Allied Mills, Inc., 450 West Wilson Bridge Road, P. O. Box 599, Worthington, Ohio 43085. Send Protests to: Justice H. Gray, Transportation Specialist, Interstate Commerce Commission, Bureau of Motor Carriers, 345 W. Wayne Street, Suite 133, Ft. Wayne, Indiana 46802.

MC 144688 (Sub-10TA), filed November 1, 1978. Applicant: READY TRUCKING, INC., 4722 Lake Mirror Place, Forest Park, GA 30050. Representative: Lavern R. Holdeman, 521 South 14th Street, P. O. Box 81849, Lincoln, NE 68501. *Sugar and corn syrup, or blends thereof*, from the facilities of Dandy Distributors, Inc., at or near Atlanta, GA, to points in the states of NC, SC, and TN, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Dandy Distributors, Inc., 1035 Donnelly Avenue, SW., P. O. Box 11496, Atlanta, GA 30310. SEND PROTESTS TO: Sara K. Davis, ICC, 1252 W. Peachtree Street, NW., Room 300, Atlanta, GA 30309.

MC 144819 (Sub-3TA), filed November 1, 1978. Applicant: C & N TRANSPORT, INC., P. O. Box 82609, Oklahoma City, OK 73108. Representative: C. L. Phillips, Room 248—Classen Terrace Building, Oklahoma City, OK 73106. *Pipeline coating materials*, except in bulk, from Madison, CT to job site locations of Seamless Pipeline Coatings, Inc., in the states of LA, AR, MO, IL, IA, WI, MN, ND, SD, NE, KS, OK, TX, NM, CO, WY, MT, ID, UT, AZ, WA, OR, CA and NV, for 180 days. SUPPORTING SHIPPERS(S): Seamless Pipeline Coatings, Inc., Box 511,

Madison, CT 06443. SEND PROTESTS TO: Connie Stanley, ICC, Room 240 Old Post Office and Court House Building, 215 NW. 3rd, Oklahoma City, OK 73102.

MC 144855 (Sub-6TA), filed November 1, 1978. Applicant: TRANS CONTINENTAL CARRIERS, INC., 169 East Liberty Avenue, Anaheim, CA 92803. Representative: David P. Christianson, 707 Wilshire Boulevard, Suite 1800, Los Angeles, CA 90017. (1) *Foodstuffs, food-treating compounds; chemicals and additives* (except in bulk), and advertising paraphernalia; and materials, equipment and supplies used in the manufacture, preparation, sales and distribution of spices, extracts, convenience foods, confectionery products, food products, salad dressing and foodstuffs (except in bulk), and (2) *commodities*, the transportation of which is exempt from regulation under the provisions of Section 203(b) of the Interstate Commerce Act, in mixed loads with the commodities described in (1) above, between facilities utilized by McCormick & Co., Inc., and its subsidiaries in the United States, on the one hand, and, on the other, points in the United States, for 180 days. SUPPORTING SHIPPER(S): McCormick and Company, Inc., 414 Light Street, Baltimore, MD 21202. SEND PROTESTS TO: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA 90012.

MC 144927 (Sub-5TA), filed November 24, 1978. Applicant: REMINGTON FREIGHT LINES, INC., (An Indiana Corporation), Box 315, U.S. 24 West, Remington, Indiana 47977. Representative: Robert B. Hebert, Harrison, Moberly & Gaston, 320 North Meridian Street, 777 Chamber of Commerce Building, Indianapolis, Indiana 46204, (317) 639-4511. *Foodstuffs*, (except in bulk), from Union City and Los Angeles, CA; Alsip and Chicago, IL; Lithonia, GA; Union, NJ and Mayland, TN to all points in the U.S., except AK and HI; and *Materials and supplies used in the manufacture of foodstuffs*, (except in bulk), from all points in the U.S., (except AK and HI), to the facilities of Griffith Laboratories, U.S.A., Inc., at Union City and Los Angeles, CA; Alsip and Chicago, IL; Lithonia, Ga; Union, NJ; and Mayland, TN, for 180 days. SUPPORTING SHIPPER: Griffith Laboratories, U.S.A., Inc., 12200 South Central Avenue, Alsip, Ill. 60658. SEND PROTESTS TO: J. G. Gray, ICC, 343 West Sayne Street, Suite 113, Fort Wayne, Ind. 46802.

MC 145174 (Sub-2TA), filed October 30, 1978. Applicant: NORTH FORTY LINES, INC., 6700 Driftwood Lane, Missoula, Mont. 59801. Representative: Bruce K. Meier (same address as applicant). Authority sought to oper-

ate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *All wood and wood products, and building materials and supplies* from all points in California, Idaho, Montana, Oregon and Washington to all points in Colorado, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Dependable Lumber & Supply Co., 1376-5th Street, Denver, Colo. 80204. SEND PROTESTS TO: District Supervisor Paul J. Labane, ICC, 2602 First Avenue North, Billings, Mont. 59101. Under a continuing contract or contracts with Dependable Lumber & Supply Co.

MC 145400 (Sub-1TA), filed November 21, 1978. Applicant: HERBERT TRUCKING, INC., Rural Route No. 1, Macon, IL 62544. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Authority sought to operate as a *contract carrier* by motor vehicle, over irregular routes, transporting: *fork lift trucks, yard tractors, trackmobiles, aerial platform lifts, and material handling equipment*, between points in AR, IL, IN, IA, KY, KS, MN, MI, MO, PA, TN and WI for 180 days, under a continuing contract or contracts with Wiese Planning & Engineering, Inc. An underlying ETA seeks 90 days authority. Supporting Shipper: WIESE PLANNING & ENGINEERING, INC., 3500 North 27th St., Decatur, IL. Send Protests To: Charles Little, District Supervisor, Interstate Commerce Commission, 4th Fl., Leland Bldg., 527 E. Capitol, Springfield, IL 62701.

MC 145515 (Sub-1TA), filed October 17, 1978. Applicant: GREENE'S CARTAGE CO., INC., 1934 Avalon Avenue, Muscle Shoals, AL 35660. Representative: Robert E. Born, Suite 508, 1447 Peachtree Street, NE, Atlanta, GA 30309. *Aluminum articles* from the facilities of Ford Motor Company at or near Sheffield, AL to Dearborn, Detroit, Hillsdale, Livonia, St. Clair, and Southfield, MI and Cleveland, Lima, Madisonville, and Sharonville, OH; and *Materials, equipment, and supplies* used in the manufacture or distribution of Aluminum articles, from Schiller Park, IL, Dearborn, Detroit, Hillsdale, Howell, Livonia, Port Huron, St. Clair and Southfield, MI and Cincinnati, Cleveland, Dayton, Fayette, Lima, Madisonville, Mt. Gilead, and Sharonville, OH to the facilities of Ford Motor Company at or near Sheffield, AL, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Ford Motor Company, 2019 Ford Road, Sheffield, AL 35660. Send protests to: Mable E. Holston, Transportation Assistant, ICC, Room 1616, 2121 Building, Birmingham, AL 35203.

MC 145566 (Sub-2TA), filed November 1, 1978. Applicant: B & K ENTERPRISES, 7950 S. 27th Street, Oak Creek, WI 53154. Representative: Terry W. Kultgen, 5605 Brookhaven Drive, Racine, WI 53406. *Shipments of heavy and specialized commodities or articles requiring special equipment or special handling outside the scope of the certificates of general commodities motor common carriers*, from the facilities of Oven Systems, Inc., New Berlin, WI, on the one hand, and, on the other all points in the States of AR and TX, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Oven Systems, Inc. 16875 W. Ryerson Road, New Berlin, WI 53151. Send protests to: Gail Daugherty, ICC, U.S. Federal Building & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 145600 (Sub-1TA), filed November 1, 1978. Applicant: JAMES A. ROLLERI, d.b.a. JIM ROLLERI TRUCKING COMPANY, P.O. Box 2374, Redding, CA 96001. Representative: Duane Roller (same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Wood pulp*, in bales from Crown Zellerbach at or near Fairhaven, Eureka, Samoa, CA to the counties of Shasta and Tehama, CA with a subsequent out-of-state movement via rail, under a continuing contract or contracts with Crown Zellerbach Corporation, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Crown Zellerbach Corporation, One Bush Street, San Francisco, CA 94119. Send protests to: A. J. Rodriguez, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 145665 (Sub-1TA), filed November 1, 1978. Applicant: QUALITY RUCK SERVICE, INC., 2784 So. Railroad Avenue, Fresno, CA 93725. Representative: Dale Mendoza (same as above). Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Fibreboard boxes*, excluding shipments in bulk or in tank vehicles, between Fresno, CA and Stockton, CA, under a continuing contract or contracts with Container Corporation of America, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Container Corporation of America, 2800 De La Cruz Boulevard, Santa Clara, CA 95050. Send protests to: Michael M. Butler, ICC, 211 Main—Suite 500, San Francisco, CA 94105.

MC 145676 (Sub-1TA), filed October 31, 1978. Applicant: JOHN BREITWEISER TRUCKING, INC., R.R. #1, Dow, IL 62022. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Authority

sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Carbonated beverages and flavored syrups*, from Granite City, IL to points in AR, IN, KS, KY, MO and TN for 180 days, under a continuing contract or contracts with Shasta Beverages, a Div. of Consolidated Foods Company. An underlying ETA seeks 90 days authority. Supporting Shipper: Shasta Beverages, a Div. of Consolidated Foods Company, P.O. Box 4617, Hayward, CA 94545. Send Protests To: Charles Little, District Supervisor, Interstate Commerce Commission, 4th Fl.—Leland Bldg., 527 E. Capitol, Springfield, IL 62701.

MC 145683 (Sub-1TA), filed December 4, 1978. Applicant: AGRO-WEST, INC., P.O. Box 594, Wilder, ID 83676. Representative: Timothy R. Stivers, P.O. Box 162, Boise, ID 83701. *BENTONITE*, from the commercial zone of Adrian, OR, to points in ID and WA, for 180 days. Applicant has filed an underlying ETA seeking up to 90 days of operating authority. Supporting Shipper: Teague Mineral Products, Route 1, Nyssa, OR 97913. Send Protests to Barney L. Hardin, ICC, 1471 Shoreline Drive, Suite 110, Boise, ID 83706.

MC 145685TA, filed November 1, 1978. Applicant: CHARLES OTTO, d.b.a. OTTO TRANSFER, 417 Elm Street, Delano, MN 55328. Representative: John B. Van de North, Jr., 2200 First National Bank Building, St. Paul, MN 55101. *Treated and untreated poles, posts, sawn timbers, pilings and lumber*, from Minneapolis/St. Paul Commercial Zone to points in OH, PA, WV, IN, MI, IL, ND, SD, MO, KS, NE, TN, KY, IA and WI, for 180 days. Supporting shipper(s): The Mac Gillis & Gibbs Co., P.O. Box 12788, New Brighton, MN 55112. Joslyn Manufacturing & Supply Company, 49th & France Avenue North, Minneapolis, MN 55422. Send protests to: Delores A. Poe, ICC, 414 Federal Building & U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 145724TA, filed October 30, 1978. Applicant: HASTINGS TRANSPORTATION, INC., East on Highway 6, Hastings, NE 68901. Representative: Thomas H. Dahlk, 1000 Woodmen Tower, Omaha, NE 68102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting (1) *Aluminum products*, from Hastings, NE and Powell, WY to all points in the United States, and *aluminum and aluminum materials*, from Oswego, NY, Lancaster, PA, Lewisport, KY, Hawesville, KY, Davenport, IA, Terre Haute, IN, McCook, IL, and Omal, OH to Hastings, NE and Powell, WY; (2) *canned and barrelled oil and grease products*,

from Oil City, PA, Bradford, PA, Kansas City, KS, Oklahoma City, OK, Houston, TX, and Port Arthur, TX to points in NE; and (3) *lumber and building products*, from Custer, SD, Worland, WY, Eugene, OR, Hood River, OR, Lakewood, CO, Billings, MT, Yakima, WA, and Wenatchee, WA to points in NE; and from Dallas, TX, Corrigan, TX, New Waverly, TX, Nacogdoches, TX, Jasper, TX, Lufkin, TX, Winnfield, LA, Natchitoches, LA, Urania, LA, Dodson, LA, Ruston, LA, Minden, LA, Plain Dealing, LA, Hammond, LA, and Crossett, AR, to points in NE, Council Bluffs, IA, Moulton, LA, Stanberry, MO, Milan, MO, Maryville, MO, Clifton Hill, MO, Kansas City, MO, Kansas City, KS, Topeka, KS, Wichita, KS, and Salina, KS, under a continuing contract or contracts with: (a) Hastings Irrigation Pipe Company; (b) Thomsen Oil Company; (c) Major Oil Company; (d) Golden Triangle Lumber Co., Inc.; and (e) American Paneling Factory Outlet, Inc., for 180 days. Supporting shipper(s): Hastings Irrigation Pipe Company, East Highway 6, Hastings, NE 68901. Send protests to: Max H. Johnston, ICC, 285 Federal Building and Court House, 100 Centennial Mall North, Lincoln, NE 68508.

MC 145725TA, filed November 1, 1978. Applicant: NATIONAL RAYSAR COURIER CORP., Route No. 2, Box 17-B, Corydon, KY 42406. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. *Laboratory specimens and laboratory reports*, between Evansville, IN, on the one hand, and, on the other, Owensboro, Hartford, Henderson, Bowling Green, Glasgow, Scottsville, Russellville, Elkton, Franklin, Hopkinsville, Madisonville, Paducah, Mayfield, and Murray, KY; Oakland City, Jasper, Washington, Vincennes, Terre Haute, Bedford, Bloomington, Huntingburg, Tell City, Rockport, and Cannellton, IN; and Lawrence, Olney, Fairfield, Mt. Carmel, Carmi, Eldorado, Harrisburg, Metropolis, Carbondale, Marion, Mt. Vernon, Centralia, Cairo, Duquoin, West Frankfort, Redbud, Pinckneyville, Herrin, and Benton, IL, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Bio-Science Laboratories, 8417 South Sherman, Indianapolis, IN 46227. Send protests to: Linda H. Sypher, ICC, 426 Post Office Building, Louisville, KY 40202.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-35680 Filed 12-21-78; 8:45 am]

[7035-01-M]

[Notice No. 234]

MOTOR CARRIER TEMPORARY AUTHORITY APPLICATIONS

DECEMBER 14, 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.

NOTE.— All applications seek authority to operate as a common carrier over irregular routes except as otherwise noted.

MOTOR CARRIERS OF PROPERTY

MC 19201 (Sub-129TA), filed October 30, 1978. Applicant: PENNSYLVANIA TRUCK LINES, INC., 49th Street & Parkside Avenue, Philadelphia, PA 19131. Representative: S. Berne Smith, 100 Pine Street, P.O. Box 1166, Harrisburg, PA 17108. *General commodities*, (except household goods in use as defined by the Commission, commodities of unusual value, Class A and B explosives, and commodities which because of size or weight require special equipment), between Cincinnati, OH, on the one hand, and, on the other, points in IN, and KY, restricted to shipments having a prior or subsequent move-

ment via rail service, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): There are approximately (10) statements of support attached to this 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 protests to: T. M. Esposito Trans. Asst., 600 Arch Street, Room 3238, Philadelphia, PA 19106

MC 24784 (Sub-16TA), filed November 3, 1978. Applicant: BARRY, INC., 463 South Water, Olathe, KS 66061. Representative: Arthur J. Cerra, 2100 TenMain Center, P.O. Box 19251, Kansas City, MO 64141. *Steel containers*, ranging in size from 3 to 57 gallons, from the facilities of Cortland Container Corp., in Kansas City, KS to the commercial zones of St. Joseph, MO; Omaha, NE; and Ponca City and Tulsa, OK, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Cortland Container Corp., Kansas City, KS. Send protests to: John V. Barry, Room 600, 911 Walnut Street, Kansas City, MO 64106.

MC 26396 (Sub-213TA), filed November 3, 1978. Applicant: POPELKA TRUCKING CO., d/b/a THE WAGONERS, P.O. Box 990, Livingston, MT 59047. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. *Lumber*, from points in AR., to points in Wyoming, Kansas, Nebraska, North Dakota, South Dakota, and points in MN., located in an north of Clay, Becker, Hubbard, Cass, Itasca and Koochiching Counties, MN., for 180 days. An underlying ETA seeks up to 90 days authority. SUPPORTING SHIPPER(S): Alvin G. Stoeger General Manager, Traffic, Chandler Corporation, P.O. Box 2840, Boise, ID 83701. SEND PROTESTS TO: Paul J. Labane DS, ICC, 2602 First Avenue North, Billings, MT 59101.

MC 30605 (Sub-163TA), filed October 19, 1978. Applicant: THE SANTA FE TRAIL TRANSPORTATION COMPANY, P.O. Box 56, 433 E. Waterman, Wichita, KS 67202. Representative: Silver, Rosen, Fischer & Stecher, 256 Montgomery, San Francisco, CA 94104. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *General commodities*, except those of unusual value, Class A & B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment, between Houston, TX, including Houston commercial zone and Dallas, TX; from Houston via Interstate Highway 45 to Dallas and return via the same route, serving no intermediate points, and serving Dallas for the purpose of joinder only.

Further restricted against the transportation of shipments where carrier's origin and destination are both within TX, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): No certificates of support was filed with this application. SEND PROTESTS TO: M. E. Taylor, ICC, 101 Litwin Building, Wichita, KS 67202.

MC 44927 (Sub-5TA), filed October 24, 1978. Applicant: RAMS EXPRESS, d/b/a PRO EXPRESS, 2910 Ross Street, Los Angeles, CA. 90058. Representative: Wyman C. Knapp, 707 Wilshire Boulevard, Los Angeles, CA. 90017. *Candy and confectionery items and accompanying advertising material*. From points in Los Angeles, CA., to points located in whole or in part in Santa Barbara, Ventura, Los Angeles, Orange and San Diego, Counties; Also from points in Los Angeles, CA., to points located in whole or in part in that portion of Riverside County bounded on the north by Interstate Highway 10 beginning with the City of Beaumont, then westerly along Interstate Highway 10 to the San Bernardino-Riverside County Line at the City of Calimesa, then westerly along the Riverside County Line to its intersection with California State Highway 31, then southerly and westerly along the Riverside County Line to its intersection with the Riverside-Orange County Boundary Line, then southerly along the Riverside-Orange County Boundary Line to its intersection with the Riverside-San Diego County Boundary Line, then easterly along the Riverside County Boundary Line to its intersection with Interstate Highway 15 (U.S. Highway 395), then northerly along Interstate Highway 15 and Interstate Temporary H Highway 15E through the City of Perris and March Air Force Base to its intersection with California State Highway 60 on the eastern boundary of the City of Riverside, then easterly on California State Highway 60 to point of beginning, and including the City of Beaumont, CA; and also from points in Los Angeles, CA., to points located in whole or in part in that portion of San Bernardino County beginning on the north at the intersection of California State Highway 30 and California State Highway 106, then westerly along California State Highway 30 to its intersection with California State Highway 83, then southerly along California State Highway 83 to California State Highway 66, then westerly along California State Highway 66 to the San Bernardino-Los Angeles County Boundary Line, then southerly along the San Bernardino County Boundary Line, then northerly and easterly along said boundary line to its intersection with California State Highway 31, then northerly and easterly along

the San Bernardino County Boundary Line to its intersection with Interstate Highway 10, then northwesterly along Interstate Highway 10 to its intersection with California State Highway 106, then northerly along California State Highway 106 to point of beginning, and including the Cities of Mentone and Yucaipa; restricted to shipments originating in Tacoma, WA., and having a prior movement to Los Angeles, CA., by rail or motor carrier, for 180 days.

NOTE.—If a hearing is deemed necessary, applicant requests it be held at Los Angeles, CA. SUPPORTING SHIPPER(S): Brown & Haley Candy Company, 1940 East 11th Street, Tacoma, WA. 98421. SEND PROTESTS TO: Irene Carlos, ICC, Room 1321 Federal Building, 300 North Los Angeles Street, Los Angeles, CA. 90012.

MC 55709 (Sub-8TA), filed November 3, 1978. Applicant: ANDING TRANSIT, INC., P.O. Box 112, Arena, WI 53503. Representative: James A. Spiegel, 6425 Odana Road, Madison, WI 53719. *Butter*, from points in WI to Charlotte, NC; Knoxville and Nashville, TN; Louisville and Springfield, KY; and Russellville, AR, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Burt Lewis, Inc., 1301 W. 22nd Street, Oak Brook, IL 60521. Send protests to: Ronald Morken, DS, 212 E. Washington Avenue, Room 317, Madison, WI. 53703.

MC 96286 (Sub-6TA), filed November 2, 1978. Applicant: ECKNOR, INC., 7 Oakcrest Drive, Huntington Station, NY 11746. Representative: Piken & Piken, One Lefrak City Plaza, Flushing, NY 11368. (1) *Animal feed*, from Tenafly, Newark, Kearny, and Secaucus, NJ, to the plantsite and storage facilities of Suffolk Agway Coop., Inc., at or near Riverhead, NY; (2) *Animal feed*, from the plantsite and facilities maintained by Dext., Inc.—Division of Scope Industries, at or near Secaucus, NJ, to points in Suffolk County, NY; (3) *Fertilizer and fertilizer materials*, (in bulk, in dump trucks), from the plantsite of Bethlehem Steel Corp., at Bethlehem, PA, to the plantsite and storage facilities of Agway, Inc., at or near Riverhead, NY., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): (1) Agway, Inc., P.O. Box 4933, Syracuse, NY. 13221. (2) Suffolk Agway Coop., Inc., 1293 Pulaski Street, Riverhead, NY 11901. (3) Dext., Inc., Div., of Scope Industries, 900 Castle Road, Secaucus, NJ. 07094. SEND PROTESTS TO: Maria B. Kejss Trans. Asst., ICC, 26 Federal Plaza, New York, NY. 1007

MC 100318 (Sub-2TA), filed September 28, 1978. Applicant: JAMES F. MOLLENHAUER, d.b.a., CITY TRANSPORT COMPANY, P.O. Box

1331, Cherry Hill, N.J. 08002. Representative: Ronald Ervais, 2520 PSFS Building, Philadelphia, Pa. 18107. *Clothing and wearing apparel*, originating at or destined to facilities of Lane Bryant, Inc., between Philadelphia, Pa., on the one hand, and, on the other, points in Deptford Township (Gloucester County), N.J., Trenton, N.J., and Newark, Del., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Lane Bryant, Inc., 12th & Chestnut Streets, Philadelphia, Pa. 19107. SEND PROTESTS TO: John P. Lynn, ICC, 428 East State Street, Room 204, Trenton, N.J. 08608.

MC 103993 (Sub-943TA), filed November 7, 1978. Applicant: MORGAN DRIVE-AWAY, INC., 28651 U.S. 20 West, Elkhart, Indiana 46515. Representative: Paul D. Borghesani, Attorney at Law, 28651 U.S. 20 West, Elkhart, Indiana 46515. *Self-propelled motor vehicles*, in secondary movements, in truckaway service from the plantsites of Alpha Vehicles, Inc., in Elkhart and LaPorte Counties, IN, to points in the United States (except AK and HI), for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Alpha Vehicles, Inc., 59140 C.R. 3 South, Elkhart, IN 46514. SEND PROTESTS TO: J. H. Gray, ICC, 343 West Wayne Street, Suite 113, Fort Wayne, IN 46802.

MC 106074 (Sub-70TA), filed November 7, 1978. Applicant: B & P MOTOR LINES, INC., P.O. Box 741, Forest City, NC 28403. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Road, Omaha, NE 68106. *Meats and packinghouse products*. From the facilities of Spencer Foods, Inc. at or near Schuyler, NE to points in NC, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Spencer Foods, Inc., P.O. Box 544, Schuyler, NE 68661. SEND PROTESTS TO: Terrell Price, ICC, 800 Briar Creek Road, Room CC-516, Mart Office Building, Charlotte, NC 28205.

MC 107541 (Sub-52TA), filed October 16, 1978. Applicant: WASHINGTON-OREGON LUMBER FREIGHTERS, INC., 12925 NE. Rockwell Drive, Vancouver, WA 98665. Representative: Edward A. Francom (same as above). *Limestone and talc*, in bags from the facilities of Pfizer, Inc., at or near Victorville and Lucerne Valley, CA to Portland, Eugene, Salem, St. Helens, McNary and Pilot Rock, OR; Salt Lake City, UT; and Seattle, WA and their respective terminal areas, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS(S): Pfizer, Inc., 235 E. 42nd Street, New York, NY 10017. SEND PROTESTS TO: R. V. Dubay, ICC, 144 Pioneer Courthouse, Portland, OR 97204.

MC 109593 (Sub-5TA), filed October 12, 1978, and published in the FEDERAL REGISTER issue of November 28, 1978, and republished as corrected this issue. Applicant: H. R. HILL, d.b.a. H. R. HILL TRUCKING COMPANY, Box 875, 2007 West Shawnee, Muskogee, OK 74401. Representative: Max G. Morgan, 223 Ciudad Building, Oklahoma City, OK 73112. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (1) *Carbonated beverages* from the facilities of Shasta Beverages, at or near Houston, TX., to points in OK and from the facilities of Shasta Beverages, at or near Lenexa, KS to points in OK, that part of TX on and north of I-20 and on and west of I-35, that part of AR on and west of U.S. Hwy. 71; and (2) *Equipment, materials, and supplies* used in the processing and distribution of carbonated beverages (except commodities which because of size and weight require special equipment), from points in OK to the facilities of Shasta Beverages at or near Houston, TX and from points in OK those in that part of TX on and north of I-20 and on and west of I-35, and that part of AR on and west of U.S. Hwy. 71 to the plantsite of Shasta Beverages at or near Lenexa, KS, under a continuing contract or contracts with Shasta Beverages, for 180 days. SUPPORTING SHIPPERS(S): Shasta Beverages, 26901 Industrial Blvd., Hayward, CA, 94545. SEND PROTESTS TO: Connie Stanley Trans. Asst., Room 240 Old Post Office & Court House Bldg., 215 NW. 3rd, Oklahoma City, OK. 73102. The purpose of this republication is to correct a portion of the territorial description which was previously omitted in the scope of the application.

MC 111201 (Sub-35TA), filed October 30, 1978. Applicant: Z. N. ZELLNER & SON TRANSFER COMPANY, P.O. Box 91247, East Point, GA. 30364. Representative: Archie B. Culbreth, 2200 Century Parkway, Suite 202, Atlanta, GA. 30345. *Plastic containers and parts for plastic containers*, from the facilities of Amoco Chemicals Corporation at or near Monroe, GA., to points in Alabama, Florida, North Carolina, South Carolina, Tennessee and W. Va., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS(S): Amoco Chemicals Corporation, 200 East Randolph Drive, Chicago, IL. 60601. SEND PROTESTS TO: Sara K. Davis Trans. Asst., ICC, 1252 W. Peachtree Street NW., Room 300, Atlanta, GA 30309.

MC 111812 (Sub-600TA), filed November 1, 1978. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: Ralph H. Jinks, P.O. Box

1233, Sioux Falls, SD 57101. *Petroleum products in packages* from Rouseville and Reno, PA to points in FL, for 180 days. SUPPORTING SHIPPERS: Pennzoil Company, Drake Building, P.O. Box 808, Oil City, PA 16301. SEND PROTESTS TO: James L. Hammond, ICC, 455 Federal Bldg., Pierre, SD 57501.

MC 114604 (Sub-57TA), filed October 30, 1978. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road NE., Atlanta, GA 30326. *Bananas and pineapples*, from Tampa, FL; Mobile, AL, and Charleston, SC, to points in Georgia, Alabama, Tennessee, Mississippi, North Carolina, South Carolina, Kentucky, Florida, Pennsylvania, Maryland, Delaware, Virginia, West Virginia, Ohio, Indiana, Michigan, Wisconsin, Illinois and Washington, D.C., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): (1) Chiquita Brands, Inc., Chestnut Ridge Road, Montville, NJ 07645. (2) Del Monte Banana Company, P.O. Box 011940, Miami, FL 33101. SEND PROTESTS TO: Sara K. Davis, Trans. Asst., ICC, 1252 W. Peachtree Street NW., Room 300, Atlanta, GA 30309.

MC 115826 (Sub-366TA), filed November 7, 1978. Applicant: W. J. DIGBY, INC., 6015 East 58th Avenue, Commerce City, CO 80022. Representative: William J. Boyd, 600 Enterprise Drive, Suite 222, Oak Brook, IL 60521. *Such commodities as are dealt in and used by producers and distributors of alcoholic beverages, liquors and wines* (except commodities in bulk in tank vehicles), between the facilities of Heublein, Inc., at or near Paducah, KY, on the one hand, and, on the other, points in the Continental United States, for 180 days. SUPPORTING SHIPPER(S): Heublein, Inc., 330 New Park Avenue, Hartford, CT 06101. SEND PROTESTS TO: H. C. Ruoff, ICC, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 115904 (Sub-133TA), filed October 30, 1978. Applicant: GROVER TRUCKING CO., 1710 West Broadway, Idaho Falls, ID 83401. Representative: Timothy R. Stivers, P.O. Box 162, Boise, ID 83701. *Mineral products in bags*, from the facilities of Industrial Mineral Ventures, Inc., located in Nye County, NV, to points in Arkansas, Arizona, Colorado, Idaho, Illinois, Iowa, Kansas, Louisiana, Minnesota, Missouri, Mississippi, Montana, Nebraska, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Tennessee, Texas, Utah, Washington, Wisconsin and WY, for 180 days. An underlying ETA seeks 90 days authori-

ty. SUPPORTING SHIPPER(S): Industrial Mineral Ventures, Inc., 5920 McIntyre Street, Golden, CO 80401. SEND PROTESTS TO: Barney L. Hardin DS, ICC, Suite 110, 1471 Shoreline Drive, Boise, ID 83706.

MC 117686 (Sub-221TA), filed October 10, 1978. Applicant: HIRSCHBACH MOTOR LINES, INC., 5000 South Lewis Boulevard, P.O. Box 417, Sioux City, IA 51102. Representative: George L. Hirschbach (Same as above). *Frozen foods*, from the facilities of Fox Deluxe Pizza Company at Joplin, MO, and the facilities of The Pillsbury Company at or near Joplin and Carthage, MO, to AZ, CA, CO, IA, MN, NE, NM, SD, TX and UT, for 180 days. SUPPORTING SHIPPER(S): Totino's Frozen Foods Division, The Pillsbury Company, 7350 Commerce Lane, Fridley, MN 55432. SEND PROTESTS TO: Carroll Russell, ICC, Suite 620, 110 No. 14th Street, Omaha, NE 68102.

MC 117872 (Sub-10TA), filed November 3, 1978. Applicant: A. JOSEPH AND COMPANY, 352 E. Woodrow Wilson, P.O. Box 4798, Jackson, MS 39216. Representative: John A. Crawford, 1700 Deposit Guaranty Plaza, P.O. Box 22567, Jackson, MS 39205. *Bananas, and coconuts and pineapples when moving in mixed loads with bananas*, from the Port of Galveston, TX to Denver, CO and points in Adams, Arapahoe, Boulder, Douglas, Jefferson and Mesa Counties, CO and that part of Weld County, CO on and south of Colorado Hwy 52, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): King Soopers, Inc., 3325 Denargo Street, Denver, CO 80216. Safeway Stores, Inc., Prepack Produce Dept., P.O. Box 5927, Terminal Annex, Denver, CO 80217. SEND PROTESTS TO: Alan C. Tarrant, ICC, Room 212, 145 East Amite Building, Jackson, MS 39201.

MC 119988 (Sub-161TA), filed October 13, 1978, and published in the FEDERAL REGISTER issue of November 22, 1978, and republished as corrected this issue. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. *Enamelware and earthenware plumbing fixtures and fittings*, from the facilities of Kohler Co., at or near Brownwood, TX to points in AZ, CA, and NV, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Kohler Co., Domestic Traffic Manager, Kohler, WI. 53044. SEND PROTESTS TO: John F. Mensing DS, 8610 Federal Bldg., 515 Rusk Ave., Houston, TX 77002. The purpose of this republication is to correct the territorial descrip-

tion which reads to points in AR, which should read as to points in AZ, which was an error in the scope of the application.

MC 121569 (Sub-1TA), filed August 11, 1978, and published in the *FEDERAL REGISTER* issue of November 14, 1978, and republished as corrected this issue.

Applicant: GATOR FREIGHTWAYS, INC. 144 W. Madison Street, Starke, FL 32901. Representative: James E. Wharton, Suite 811, Metcalf Building, 100 S. Orange Avenue, Orlando, FL 32801. Authority sought to operate as a common carrier, by motor vehicle, over regular routes, transporting: General commodities (except those of unusual value, Class A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between all points in FL excluding all points west of Lake City, FL over the following routes, serving all intermediate points except as shown: Between Jacksonville and the FL-GA State Line via State Road 15 (U.S. 1) and State Road 5 (U.S. 170) serving all intermediate points. Between Jacksonville and Miami via State Road 5 (U.S. 1) serving all intermediate points and the off-route points in Allenhurst, Artesia, Canaveral, Canaveral Beach, Canaveral Harbor, Cocoa Beach, Courtney, Fellsmere, Georgiana, Indiantown, Jesen Beach, Lotus, Melbourne Beach, Patrick Air Force Base, Port Canaveral, Shiloh, Titusville Beach, Tropic and Wilson. Between Bunnell and Flagler Beach via State Road 100 serving intermediate points and the off-route points of the Lehigh Portland Cement Co., Inc. Bunnell to junction of State Road 11 and U.S. 92 and DeLand via State Roads 11 and 15. Between West Palm Beach and the junction of State Roads 7 and 84, west of Ft. Lauderdale via State Roads 80 and 7. Between Ft. Lauderdale and Miami via State Roads 84 and 7. Between Miami and Deerfield Beach via State Roads 7 and 810. Between Deerfield Beach and West Palm Beach on State Roads 808 and 809 (200) as an alternate to State Road 5. Between Daytona Beach and St. Petersburg via State Road 600 or U.S. 92 by way of DeLand, Sanford, Orlando, Kissimmee, Haines City, Lakeland, Tampa and Gandy Bridge. Between Tampa and St. Petersburg by way of Safety Harbor on State Roads 580 and 593 and U.S. 19. Between Orlando and Indian River City over State Road 50. Between Orlando, and Kissimmee via State Road 527 as an alternate route. Between Orlando, Mount Dora, Tavares, Eustis, Leesburg, Groveland, Clermont, Winter Garden and Orlando over U.S. 441 and State Roads 19, 44, 33, and 50. Between Orlando and Geneva via State Roads 418 and 426. Between Kis-

simmee and Melbourne via State Road 500. Between Haines City and Auburndale via State Road 544 to Winterhaven and 559 to Auburndale serving Eagle Lake and Eloise as off-route points to Winter Haven. Between Tampa and Plant City via State Road 574 as an alternate route. Between Lakeland and Haines City by way of Bartow via U.S. 98, State Road 60 and U.S. 27, serving intermediate points, including Eagle Lake and Eloise. Between Tampa and Clearwater via State Road 60 by way of Davis Causeway. Between Tampa, St. Petersburg and Pass-A-Grille via State Roads 580, 584, 590, 55, 689, 694, 699 and County Roads to Dunedin, Largo, Pasadena, Gulfport, Pass-A-Grille and Pinellas Park. Between Tampa and Mantee via State Road 43 (U.S. 301) serving intermediate points and the off-route points of Wimouma. Between Tampa and Sarasota via State Road 45 (U.S. 41) serving the intermediate and off-route points of Ruskin, Sun City, Gillett, Palmetto, Gibsonton, Piney Point, Terra Ceia, Rubonia, Palma Sola, Bradenton, Cortez, Bradenton Beach, Oneco, Gates City, Fruitville, Willow Station and Ellenton. Over East Sand Lake Road running Westward from a junction with U.S. 17 approximately 4 miles south of Orlando to Doctor Phillips, serving intermediate points between the junction of U.S. 17 and East Sand Lake Road through and including Doctor Phillips, FL. Between Haines City and Lake Placid via State Road 17, serving Lake Hamilton, Dundee, Lake Wales, Frostproof, Avon Park and Sebring. Between Tampa and Arcadia via State Roads 60 and 35 (U.S. 17) serving Brandon, Hopewell, Mulberry, Pierce, Bradley Junction, Bartow and Pembroke. Between Winter Haven and Dundee via State Road 542 with service to the off-route of Alturas and Connersville. Between Haines City and Lake Placid via State Road 25. Between Lake Wales and junction of State Road 60 and the Kissimmee River via State Road 60, serving all intermediate points and off-route points within 4 miles of said junction; also, from Frostproof to the intersection of State Roads 630 and 60 via State Road 630, serving all intermediate points including Indian Lake Estates. Serving the General Portland Cement Company located nineteen (19) miles west of Miami, on Krome Avenue, 3 and 1/2 miles south of Tamiami Trail, and the Lehigh Portland Cement Company, located approximately seven (7) miles west of Miami International Airport and 2 miles north of the Tamiami Trail as off-route points in connection with the carriers authority to serve Miami, FL. Serving Pratt and Whitney Division of United Aircraft, located approximately 8 miles west of Jupiter as

an off-route point in connection with the carriers present authority. Alternate route between Okeechobee and Jupiter via State Roads Nos. 710 and 706 by way of Indiantown; also, between Indiantown and U.S. 1 via extension of State Road 710. Between Sarasota and Naples, using U.S. Highway 41, serving all intermediate points and also serving Englewood and Cape Coral as off-route points and with the right of joinder (or tacking) at all points in connection with presently authorized routes. Between Naples and Miami, using U.S. Highway 41, serving no intermediate points and using Interstate Highway 95 and Florida State Road 84 as an alternate route for operating convenience only, with right of joinder (or tacking) to all points in connection with presently authorized routes. Between Miami on the one hand and Florida City on the other via U.S. Highway 1, State Road 826, and Florida Turnpike, serving all intermediate points and also serving all points on and east of State Road 27 as off-route points.

The following described authority shall be for closed door and operating convenience only, as follows: Between Lebanon Station and Dunedin via State Road 55 (U.S. 19), with closed doors. Between junction of State Road 55 (U.S. 19), State Road 700 and Brooksville via State Road 700 with closed doors. From junction of U.S. 1 and State 1 and State Road A1A near Jupiter, over State Road A1A to Lake Park; thence from Lake Park and also from intersection of county roads with State Road A1A over county roads to intersection with State S-809 and thence over State Road S-809 to intersection with State Road 80 (at a point about 4 miles west of West Palm Beach) and return over same routes as an alternate route for operating convenience serving no intermediate points. From the intersection of State Road 60 and the Kissimmee River via State Road 60 to Vero Beach and return over the same route, serving no intermediate points, as an alternate route for operating convenience. (a) Between Jacksonville and Deland via U.S. 17. (b) Between Bunnell and Lake City via State Road 100. (c) Between Holopaw and Miami via U.S. 441 and U.S. 27 by way of south Bay. (d) Between West Palm Beach and Belle Glade via State Road 80. (e) Between Tampa and Waldo via U.S. 301. (f) Between Lakeland and Dade City via U.S. 98. (g) Between Leesburg and Inverness via State Road 44. (h) Between Okahumpka and Floral City via State Road 43. (i) Between Leesburg and Williston via U.S. 27. (j) Between Williston and Lebanon Station via State Road 121, with closed doors at all intermediate points and Belle Glade, Dade City, Floral City, Inverness, and

Waldo, Between Cocoa and junction of State Roads 50 and 520 (near Bithlo) via State Road 520 as an alternate route for operating convenience only. Between junction of State Roads 24 and 121 (near Gainesville, FL) via State Road 121 to Williston, FL and return over the same route, serving no intermediate points. Between Canal Point and junction of U.S. 98 and U.S. 441 via U.S. 98, serving no intermediate points and for operating convenience only. Between Okeechobee, FL and Sebring, FL via U.S. 98 to junction with U.S. 27; thence via U.S. 27A to Sebring, serving no intermediate points and return over the same route. Between Avon Park, FL, via State Road 64 to junction with U.S. 301, serving no intermediate points, and return over the same route. Between Starke, FL, and Tampa, FL, via State Road 24, from Stark to Archer and State Road 45 (U.S. 41) from Archer to Tampa, serving no intermediate points and return over the same route, as an alternate route for operating convenience only, and with right of joinder at all points in connection with presently authorized routes. Between Miami, FL, and Parrish, FL, via U.S. 41 to junction with State Road 29, thence via State Road 29 to junction with State Road Alternate 29 to junction with State Road 29 (north of Immokalee); thence via State Road 29 to junction with State Road 82; thence via State Road 82 to junction with unnumbered road (near Ft. Myers), thence via unnumbered road to Tice, FL, thence from Tice via State Road 80 to junction with State Road 31; thence via State Road 31 to Arcadia, FL; thence via State Road 70 to junction with State Road 675; thence via State Road 675 to junction with U.S. 301 at Parrish, FL, and return over same route, as an alternate route for operating convenience only. Between South Bay and Lake Placid, FL, via U.S. 27 and between West Frostproof, FL, and Fort Meade, via U.S. 98 as alternate routes for operating convenience only. Between Harrisburg, FL, and Punta Gorda, FL via State Roads 29, 74 and U.S. 17 to Punta Gorda, and return over the same route, as an alternate route for operating convenience only. Between junction U.S. 27 and State Road 70 (near Childs) to junction State Road 72 and U.S. 41 (near Sarasota) via State Road 70 to Arcadia and State Road 72 to junction with U.S. 41 by way of Arcadia, serving Harrisburg, State Road 72 to junction with U.S. 41 by way of Arcadia, serving Harrisburg, Arcadia, junction U.S. 27 and State Road 70; junction State Road 70 and State Road 31, junction State Road 72 and U.S. 41, in connection with the above described routes for purpose of joinder only. No duplicating authority sought.

Alternate route between Brooksville and Groveland over State Road 50. Service not authorized at intermediate points and serving Brooksville, FL, for purpose of joinder only, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): There are 33 statements of 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: G. H. Fauss, Jr., ICC, P.O. Box 35008, 400 W. Bay Street, Jacksonville, FL 32202.

MC 125506 (Sub-32TA), filed November 3, 1978. Applicant: JOSEPH ELETTO TRANSFER, INC., 33 West Hawthorne Avenue, Valley Stream, NY 11580. Representative: Bruce J. Robbins, Robbins & Newman, 118-21 Queens Boulevard, Forest Hills, NY 11375. Authority sought to operate as a contract carrier by motor vehicle, over irregular routes, transporting: Such merchandise as is dealt in by retail specialty shops, and advertising, display materials, store fixtures and furniture, between shipper's stores, distribution centers and warehouses located in the New York, NY Commercial Zone, and Rockaway, NJ., under a continuing contract, or contracts, with Lane Bryant, for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Lane Bryant, 1501 Broadway, New York, NY 10036. Send protests to: Maria B. Kejss Trans. Asst., ICC, 26 Federal Plaza, New York, NY 10007.

MC 125996 (Sub-62TA), filed November 7, 1978. Applicant: ROAD RUNNER TRUCKING, INC., 2225 South 400 West, Salt Lake City, UT 84115. Representative: John P. Rhodes, P.O. Box 5000, Waterloo, IA 50704. Meats, meat products, meat by-products and articles distributed by meat packing houses (except hides and commodities in bulk), from the facilities of George A. Hormel & Co., at Austin and Minneapolis-St. Paul commercial zone, MN, and Ft. Dodge and Ottumwa, IA, to points in AZ, OR, UT, WA, and CO, for 180 days. Supporting shipper(s): George A. Hormel & Co., P.O. Box 800, Austin, MN 55912. Send protests to: L. D. Helfer, ICC, 5301 Federal Building, Salt Lake City, UT 84138.

MC 126118 (Sub-107TA), filed October 30, 1978. Applicant: CRETE CARRIER CORPORATION, P.O. Box 81228, Lincoln, NE 68501. Representative: Duane W. Acklie (same address as applicant). Those commodities used by and dealt in by the General Electric Company, (except bulk and size and weight commodities), (1) From Ontario, CA, and Seattle, WA, and their commercial zones, to points in the

United States on and east of U.S. Highway I-35. (2) From Brockport, NY, and Allentown, PA, and their commercial zones, to points in the United States in and west of WI, IL, MO, OK, and TX, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): A. H. Liftman Manager, Transportation Services and Distribution, Housewares, and Audio General Electric Company, 1205 Boston Avenue, Bridgeport, CT 06602. Send protests to: Max H. Johnston DS, 285 Federal Building and Courthouse, 100 Centennial Mall North, Lincoln, NE 68508.

MC 126673 (Sub-3TA), filed October 24, 1978. Applicant: RENO G. RICCI, d/b/a RICCI BROTHERS TRUCKING, 600 Stage Gulch Road, Petaluma, CA 93952. Representative: Raymond A. Greene, Jr., of Handler, Baker & Greene, 100 Pine Street, Suite 2550, San Francisco, CA 94111. Authority sought to operate as a contract carrier, by motor vehicle, over irregular routes, transporting: Processed animal and poultry feed, (in bulk), between Petaluma, CA and Yerrington, NV, under a continuing contract, or contracts, with Hunt Behrens, Inc., for 180 days. Supporting shipper(s): Hunt Behrens, Inc. Send protests to: A. J. Rodriguez DS, ICC, San Francisco, CA 94111.

MC 126717 (Sub-13TA), filed November 3, 1978. Applicant: WALT'S DRIVE-A-WAY SERVICE, INC., 1103 East Franklin Street, Evansville, IN 47711. Representative: Warren C. Moberly, 777 Chamber of Commerce Building, Indianapolis, IN 46204. Mine, quarry, and well drilling machinery, in drive-away movement, from Enid, OK to all points and places in the U.S. including AK, except HI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Koehring Speedstar Division, 1200 N. 52nd Street, Enid, OK 73701. Send protests to: Beverly J. Williams, ICC, Federal Building and U.S. Courthouse, 46 East Ohio Street, Room 429, Indianapolis, IN 46204.

MC 126844 (Sub-59TA), filed November 3, 1978. Applicant: R.D.S. TRUCKING CO., INC., 1713 North Main Road, Vineland, NJ. 08360. Representative: Kenneth F. Dudley, 611 Church Street, P.O. Box 279, Ottumwa, IA 52501. Canned food products, from the plantsite and facilities of Campbell Soup Co., at or near Napoleon, OH, to points in Indiana, Kentucky, Michigan, New York, Pennsylvania, Chicago, IL., and Camden, NJ., for 180 days. SUPPORTING SHIPPER(S): Campbell Soup Co., Napoleon, OH. 43545. SEND PROTESTS TO: John P. Lynn Trans. Asst., ICC, 428 East State Street, Room 204, Trenton, NJ. 08608.

MC 127811 (Sub-16TA), filed November 2, 1978. Applicant: BRYNWOOD TRANSFER, INC., 175 8th Avenue, Southwest, New Brighton, MN 55112. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. *Power transmission equipment and materials, supplies and equipment used in the installation or repair thereof*, between points in MN, WI, ND, and SD, for 180 days. SUPPORTING SHIPPER(S): Northern States Power Co., 414 Nicollet Mall, Minneapolis, MN 55401. SEND PROTESTS TO: Delores A. Poe, ICC, 414 Federal Building and U.S. Court House, 110 South 4th Street, Minneapolis, MN 55401.

MC 129600 (Sub-31TA), filed November 1, 1978. Applicant: POLAR TRANSPORT, INC., 176 King Street, Hanover, MA 02339. Representative: Frank J. Weiner, 15 Court Square, Boston, MA 02108. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Confectionery*, (except in bulk) in vehicles equipped with mechanical refrigeration, from the facilities of Schrafft Candy Company in Middlesex and Suffolk Counties, MA; Deran Confectionery, Division of Borden, Inc., in Middlesex and Suffolk Counties, MA, and North Grosvenordale, CT and Nabisco Confections, Inc., subsidiary of Nabisco, Inc., in Bristol, Middlesex and Norfolk Counties, MA, and Ashton, RI, to points in CA, CO, OR, and WA, under a continuing contract or contracts with The Schrafft Candy Co., for 180 days. SUPPORTING SHIPPER(S): Schrafft Candy Company; Deran Confectionery, Division of Borden, Inc., and Nabisco Confections, Inc., subsidiary of Nabisco, Inc. SEND PROTESTS TO: John B. Thomas, ICC, 150 Causeway Street, Boston, MA 02114.

MC 133453 (Sub-17TA), filed October 30, 1978. Applicant: TROJAN TRANSPORTATION, INC., 1616 Walnut St., 24th Floor, Philadelphia, PA. 19103. Representative: Richard M. Ochroch, 316 S. 16th Street, Philadelphia, PA. 19103. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such merchandise as is dealt in by wholesale, chain, grocery, department stores and food business houses and in connection therewith equipment, materials and supplies used in the conduct of such business (except glass containers and commodities in bulk)*, between points in Connecticut, Delaware, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Virginia, North Carolina, South Carolina, West Virginia, Georgia, Florida, Alabama, Louisiana, Mississippi, Tennessee and the District of

Columbia. RESTRICTION: Limited to a transportation service to be performed, under a continuing contract, or contracts, with Food Fair, Inc., Ideal Shoe Co., and J. M. Fields, Inc., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Food Fair, Inc., J. M. Fields, Inc., Ideal Shoe Co., 3175 JF Kennedy Blvd., Philadelphia, PA. 19104. SEND PROTESTS TO: T. M. Esposito Trans. Asst., 600 Arch Street, Room 3238, Philadelphia, PA. 19106.

MC 133655 (Sub-130TA), filed November 7, 1978. Applicant: TRANSNATIONAL TRUCK, INC., P.O. Box 31300, Amarillo, TX 79120. Representative: Warren L. Troupe, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. *Such commodities as are dealt in by manufacturers and distributors of floor coverings from Cerritos and City of Industry, CA to the facilities of Longhorn Service & Supply Company at Amarillo, Lubbock and El Paso, TX and Albuquerque, NM*, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER: Longhorn Service & Supply Co., 2701 Line Avenue, Amarillo, TX 79101 (Claud Foster). SEND PROTESTS TO: Haskell E. Ballard, ICC, Herring Plaza, Box H-4395, Amarillo, TX 79101.

MC 133655 (Sub-135TA), filed October 12, 1978. Applicant: TRANSNATIONAL TRUCK, INC., P.O. Box 31300, Amarillo, TX 79120. Representative: Warren L. Troupe, 2480 E. Commercial Boulevard, Fort Lauderdale, FL 33308. *Chocolate coating, confectionery, beverage preparations, milk and milk chocolate and cocoa compounds*, from Burlington, WI to Dallas and Houston, TX, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): The Nestle Company, Inc., 100 Bloomingdale Road, White Plains, NY 10605. Send protests to: Haskell E. Ballard, ICC, Box F-13206 Federal Building, Amarillo, TX 79101.

MC 135052 (Sub-13TA), filed November 3, 1978. Applicant: ASHCRAFT TRUCKING, INC., 875 Webster Street, Shelbyville, IN 46176. Representative: Warren C. Moberly, 320 North Meridian Street, Indianapolis, IN 46204. *Mineral wool and insulation products and materials*, from Shelbyville, IN to all points in AL, AR, CT, DE, FL, GA, KS, LA, ME, MA, MN, MS, NE, NH, NJ, NC, OK, RI, SC, TN, TX, VT and VA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Knauf Fiber Glass, 240 Elizabeth Street, Shelbyville, IN 46176. Send protests to: Beverly J. Williams, ICC, Federal Building and U.S. Courthouse, 46 East Ohio Street, Room 429, Indianapolis, IN 46204.

MC 135231 (Sub-28TA), filed November 2, 1978. Applicant: NORTH STAR TRANSPORT, INC., Route 1, Highway 1 and 59 West, Thief River Falls, MN 56701. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. *Snowmobiles, and parts and accessories thereof*, from Crosby, MN, to points in IL, IN, WI, MI, NY, PA, NH, VT, ME, MA, CO, CT, OH, ND, SD, WA, IA, MT, ID, UT and ports of entry located on the United States-Canadian Borders in MI, NY, ME, and ND, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Arctic Enterprises, Inc., Thief River Falls, MN 56701. Send protests to: Ronald R. Mau, ICC, Room 268 Federal Building and U.S. Post Office, 657 2nd Avenue North, Fargo, ND 58102.

MC 135691 (Sub-26TA), filed November 2, 1978. Applicant: DALLAS CARRIERS CORP., 3610 Garden Brook Drive, Box 34080, Dallas, TX 75234. Representative: J. Max Harding, P.O. Box 82028, Lincoln, NE 68501. *Drugs and animal feed supplements (except commodities in bulk)* from Nutley, Belvidere and Branchburg, NJ to Dallas and Fort Worth, TX, and San Leandro and Fresno, CA, for 180 days. Restriction: Restricted to transportation service to be performed under a continuing contract or contracts with Hoffmann-LaRoche, Inc. Supporting shipper(s): Hoffmann-LaRoche, Inc., 340 Kingsland Street, Nutley, NJ 07110. Send protests to: Opal M. Jones, ICC, 1100 Commerce Street, Room 13C12, Dallas, TX 75242.

MC 135797 (Sub-161TA), filed November 7, 1978. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 200, Lowell, AR, 72745. Representative: Paul R. Bergant (same as above). *Canned goods*, from the facilities of Green Giant Company at Denton, TX to points in AR, LA, MS and OK, for 180 days. Restricted to traffic originating at the named origins and destined to the named destinations. Supporting shipper(s): Green Giant Company, Le Sueur, MN 56058. Send protests to: William H. Land, Jr., 3108 Federal Office Building, 700 West Capitol, Little Rock, AR 72201.

MC 136325 (Sub-3TA), filed November 3, 1978. Applicant: CUFURAY, LTD., Route 1, Box 333, Delavan, WI 53115. Representative: David V. Purcell, 111 E. Wisconsin Avenue, Milwaukee, WI 53202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Metal containers and container ends, and materials, equipment, and supplies used in the manufacture and distribution of the foregoing commodities, (except commodities in bulk)*, between the facilities of Del Monte Corporation at or near Plover, WI, on the

one hand, and, on the other, Wells and Sleepy Eye, MN, under a continuing contract or contracts, with Del Monte Corporation, for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Del Monte Corporation, P.O. Box 89, Rochelle, IL 61068. Send protests to: Gail Daugherty Trans. Asst., ICC, U.S. Federal Bldg., & Courthouse, 517 East Wisconsin Avenue, Room 619, Milwaukee, WI 53202.

MC 136611 (Sub-2TA), filed October 30, 1978. Applicant: RED & WHITE MARKET & TRANSFER, INC., 1214 East South Street, Hastings, NE. 68901. Representative: Lavern R. Holdeman, P.O. Box 81849, Lincoln, NE. 68501. *Iron and steel articles*, from points in the states of Ohio, Pennsylvania, and W. VA., to Hastings, NE., for 180 days. Supporting shipper(s): Paul D. Bosworth Traffic Manager-Production, Dravo Corporation, Neville Island, PA. 15225. Send protests to: Max H. Johnston DS, 285 Federal Building & Court House, 100 Centennial Mall North, Lincoln, NE. 68508.

MC 138572 (Sub-6TA), filed November 2, 1978. Applicant: BRUNSWICK PETROLEUM TRANSPORT LTD., McAllister Industrial Park, P.O. Box 132, Saint John, New Brunswick, Canada. Representative: J. P. Vermette, 7887 Grenache Street, Ville d'Anjou, Quebec, Canada. *Fuel oil additive*, (in bulk, in tank vehicles), from Bridgeport, CT., to the Port of Entry on the International Boundary Line between the United States and Canada located at Calais, ME., restricted to the transportation of traffic in foreign commerce destined to New-Brunswick and Nova Scotia, Canada, for 180 days. Supporting shipper(s): Martin Marietta Chemicals, Refractories Div., Executive Plaza II, Hunt Valley, MD. 21030. Send protests to: ICC, 76 Pearl Street, Room 305, Portland, ME. 04111.

MC 138960 (Sub-6TA), filed November 3, 1978. Applicant: ROKO EXPRESS, INC., P.O. Box 169, 2545 Parsons Avenue, Columbus, OH 43216. Representative: H. Barney Firestone, 10 South LaSalle Street, Chicago, IL 60603. *Household aluminum foil*, from Mufreesboro, TN to Plymouth, MI; Ft. Wayne, IN; Atlanta, GA; Greenville, SC; Raleigh and Charlotte, NC; Edison, Woodbridge and Elizabeth, NJ; and Central Islip, NY, for 180 days. Supporting shipper(s): Benham & Company, Inc., P.O. Box 29, Mineola, TX 75773. Send protests to: Frank L. Calvary, ICC, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, OH 43215.

MC 139482 (Sub-72TA), filed October 31, 1978. Applicant: NEW ULM FREIGHT LINES, INC., P.O. Box 877, New Ulm, MN 56073. Representative:

James E. Ballenthin, 630 Osborn Bldg., St. Paul, MN 55102. *Glazed clay tile*, from the plantsite and facilities of Sikes Corporation at or near Lawrenceburg, KY., to points in the states of Minnesota, North Dakota, South Dakota, Iowa, Illinois, Nebraska, Colorado, Kansas, Missouri, Texas, Oklahoma, Louisiana, Mississippi, Alabama and AR., for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Sikes Corporation, P.O. Box 447, Lakeland, FL 33802. Send protests to: Delores A. Poe Trans. Asst., ICC, 414 Federal Bldg., & U.S. Court House, 110 South 4th Street, Minneapolis, MN. 55401.

MC 139458 (Sub-2TA), filed September 27, 1978. Applicant: RICHNER, INC., P.O. Box 1488, Durango, Colo. 81301. Representative: J. Albert Sebald, 1700 Western Federal Building, Denver, Colo. 80202. *Coal*, (in bulk), from the mine of Arness-McGriffin Coal Company about 4 miles west of Durango, La Plata County, Colo., on U.S. Highway 160, to the Hanna rail siding on U.S. Highway 160 about 6 miles west of Del Norte, Rio Grande County, Colo., for 180 days. Supporting shipper(s): Arness and McGriffin Coal Co., 1139 Main Avenue, Durango, Colo. 81301. Send protests to: H. C. Ruoff, ICC, 492 U.S. Customs House, 721 19th Street, Denver, Colo. 80202.

MC 142649 (Sub-8TA), filed November 3, 1978. Applicant: H. O. SMESTAD CO., P.O. Box 2904, Great Falls, MT 59403. Representative: G. Robert Crotty, Jr., 400 First Nat'l Bank Bldg., Great Falls, MT 59401. *Malt and carbonated beverages and related advertising materials, equipment and supplies*, from Cold Spring, MN., to Arizona, California, Colorado, Idaho, Oregon, Texas, Utah and WA., for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Roman DeWenter Secretary, Cold Spring Brewing Co., Cold Spring, MN. Send protests to: Paul J. Labane DS, ICC, 2602 First Avenue North, Billings, MT. 59101.

MC 142864 (Sub-3TA), filed November 2, 1978. Applicant: RAY E. BROWN TRUCKING, INC., P.O. Box 501, Massillon, OH 44646. Representative: Jerry B. Sellman, 50 West Broad Street, Columbus, OH 43215. *Charcoal briquettes, boxed fireplace coal, fireplace logs, fuel lighting liquids and advertising materials*, from Sebring, Canton and Alliance, OH; Paris and Cotter, AR; Louisville, KY; Salem, MO; and Princeton, NJ, to points in AR, CT, FL, GA, IL, IN, MA, MO, MI, NJ, NY, NC, OH, PA, SC, VA, WV, and WI, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Sebring Forest Industries, Inc., P.O. Box 230, Sebring,

OH 44672. SEND PROTESTS TO: Frank L. Calvary, ICC, 220 Federal Building and U.S. Courthouse, 85 Marconi Boulevard, Columbus, OH 43215.

MC 143059 (Sub-28 TA), filed October 3, 1978, and published in the FR issue of November 22, 1978, and republished as corrected this issue. Applicant: MERCER TRANSPORTATION COMPANY, 40211 12th & Main St., P.O. Box 35610, Louisville, KY 40232. Representative: Clint Oldham, 1108 Continental Life Bldg., Ft. Worth, TX 76102. *Used railroad ties*, from points in MT, to points in CA and NV., for 180 days. An underlying ETA seeks 90 days of authority. SUPPORTING SHIPPER(S): Jerry Higgins, Secretary-Treasurer, Quality Enterprises, Inc., 4101 West Capitol Avenue, Sacramento, CA 95691. SEND PROTESTS TO: Mrs. Linda H. Sypher DS, ICC, 426 Post Office Bldg., Louisville, KY 40202. The purpose of this republication is to correct from points in MT, instead of from points in MO, which was an error in the territorial description.

MC 143127 (Sub-18TA), filed November 3, 1978. Applicant: K. J. TRANSPORTATION, INC., 1000 Jefferson Road, Rochester, NY 14623. Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202. *Plastic*, (except in bulk), from Owensboro, KY, to points in the United States in and east of Minnesota, Iowa, Missouri, Arkansas and LA, and (except KY), for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Hammond Plastics-Midwest, Inc., Mr. Raymond L. Biscopink, Sales Acct., Mgr. P.O. Box 990, Owensboro, KY 42301. SEND PROTESTS TO: ICC, U.S. Courthouse & Federal Bldg., 100 S. Clinton Street, Room 1259, Syracuse, NY 13260.

MC 143267 (Sub-35TA), filed October 6, 1978. Applicant: WEAVER TRANSPORTATION COMPANY, 5452 Oakdale Road, Smyrna, GA. Representative: James L. Brazzee, Jr., 3355 Lenox Road No. 795, Atlanta, GA 30326. *Mortar and cement mixes; dry concrete mix* (cement mix with sand and gravel and other ingredients); *cement mortar mix, portland cement, fly ash* (in bag form), *fly ash cement and/or lime, sand, rock or stone, crushed, ground or natural, acrylic paints, masonry cement*, either palletized or unpalletized in containers (glass, paper bags, paper board, fibre board, metal or plastic buckets) in mixed or solid truck loads, from the plant site of Williams Brothers Concrete, Inc., located in Atlanta, Fulton County, GA, to points in AL, SC, NC, TN, FL, VA and MS, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Williams Brothers Concrete, Inc., 934

Glanwood Ave., Atlanta, GA 30316. SEND PROTESTS TO: Sara K. Davis, ICC, 1252 W. Peachtree St., NW., Rm. 300, Atlanta, GA 30309.

MC 143267 (Sub-41TA), filed November 7, 1978. Applicant: CARLTON ENTERPRISES, INC., 4588 State Route 82, Mantua, OH 44255. Representative: Peter A. Greene, 900 17th Street, NW., Washington, D.C. 20006. *Refractory products* from the facilities of Kaiser Aluminum & Chemical Corp., Refractories Division at Mexico, MO, to points in CT, DE, KY, MD, MI, NJ, NY, OH, PA, VA, WV and WI, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Kaiser Aluminum & Chemical Sales, Inc., Box 544, Bridgeview, IL 60455. Send protests to: ICC, 731 Federal Building, Cleveland, OH 44199.

MC 143268 (Sub-5TA), filed November 3, 1978. Applicant: TROCHU TRUCKING SERVICES, LTD., 915-48th Avenue SE., Calgary, AB, Canada. Representative: Charles E. Johnson, P.O. Box 1982, Bismarck, ND 58501. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Hog and poultry feeding and handling equipment and materials*, from Birmingham, AL; Bowling Green, KY; Holland, MI and their commercial zones, to ports of entry on the International Boundary line between Canada and the United States located in ND and MT., for furtherance to points in AB. RESTRICTION: Restricted to a transportation service to be performed under a continuing contract or contracts, with Walbern Agri Systems, Ltd., Linden, AB, Canada, for 180 days. An underlying ETA seeks up to 90 days authority. SUPPORTING SHIPPERS(S): Lloyd Harder Marketing Service Manager, Walbern Agri-Systems, Ltd., Box 250, Linden, AB, Canada TOM 1GO. SEND PROTESTS TO: Paul J. Labane DS, ICC, 2602 First Avenue North, Billings, MT 59101.

MC 143775 (Sub-28TA), filed November 2, 1978. Applicant: PAUL YATES, INC., 6601 W. Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same as above). *Fruit juices and apple products* (except liquids in bulk), from the facilities of Tree Top, Inc., Cashmere, Selah, and Wenatchee, WA and points in their respective commercial zones, to AZ, CA, ID, NV, OR, and UT, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS(S): Tree Top, Inc., P.O. Box 248, Selah, WA 98942. SEND PROTESTS TO: Andrew V. Baylor, ICC, Room 2020 Federal Building, 230 N. First Avenue, Phoenix, AZ 85025.

MC 143775 (Sub-32TA), filed November 7, 1978. Applicant: PAUL YATES,

INC., 6601 W. Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same as above). *Candy and confectioneries in vehicles equipped with mechanical refrigeration* (except in bulk), from the warehouses and plantsites of E. J. Brach & Sons, Chicago, IL and its commercial zone, to points in PA, NY, NJ, VA, MD, GA, MA, CT and TX, for 180 days. RESTRICTED to traffic originating in the above named origin. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPERS(S): E. J. Brach & Sons, 4656 W. Kinzie, Chicago, IL 60644. SEND PROTESTS TO: Andrew V. Baylor, ICC, Room 2020 Federal Building, 230 N. First Avenue, Phoenix, AZ 85025.

MC 144122 (Sub-32TA), filed November 2, 1978. Applicant: CARRETTA TRUCKING, INC., South 160 Route 17 North, Paramus, NJ 07652. Representative: Charles J. Williams, 1815 Front Street, Scotch Plains, NJ 07076. *Foodstuffs* (except commodities in bulk) in vehicles equipped with mechanical refrigeration, from points in CA, ID, OR and WA to the facilities used by the Flagstaff Corp., at or near Marlboro, Perth Amboy and Trenton, NJ, Baltimore, MD, and Attleboro and Boston, MA, for 180 days. SUPPORTING SHIPPERS(S): Flagstaff Foodservice Group, 530 Fayette Street, Perth Amboy, NJ 08861. SEND PROTESTS TO: Joel Morrrows, ICC, 9 Clinton Street, Newark, NJ 07102.

MC 144747 (Sub-2TA), filed October 24, 1978. Applicant: INTERSTATE EQUIPMENT CO., INC., 22821 N. 81st Avenue, Peoria, AZ. 85345. Representative: Lewis P. Ames, Phil B. Hammond, Shimmel, Hill, Bishop & Gruender, 10th Floor, 111 W. Montoe, Phoenix, AZ. 85003. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: (A) *Materials, equipment and supplies* used or useful in the manufacture of wooden flush doors: (1) from points in the United States, (except Alaska and Hawaii), to the facilities of Walled Lake Door Company at Tupelo, MS, Cameron, TX, Mobile, AL and Orange, CA; (2) between the facilities of Walled Lake Door Company at Tupelo, MS, Cameron, TX, Mobile, AL, Orange, CA, Jasper, FL and Savannah, GA; and (B) *Wooden flush doors and components parts, thereof*, from the facilities of Walled Lake Door Company at (1) Tupelo, MS, to points in Illinois, Wisconsin, Minnesota, Iowa, Michigan, Indiana, Ohio, North Carolina, Georgia, Alabama, and FL; (2) Orange, CA, to points in Arizona, Nevada, New Mexico, Utah, Colorado, Oregon, and WA; (3) Cameron, TX, to points in Arkansas, Missouri, Illinois, Kansas, Colorado, Nebraska, North Dakota,

South Dakota, Minnesota, Oklahoma, and IA; (4) Mobile, AL, to points in Georgia, Florida, Texas, Louisiana, Oklahoma, Kansas, Nebraska, North Dakota, South Dakota, Colorado, Minnesota, Wisconsin, and ID., restricted in (A) and (B) above to the transportation if shipments originating at or destined to the facilities of Walled Lake Door Company and to the transportation of shipments moving under a continuing contract or contracts, with Walled Lake Door Company of Phoenix, AZ., for 180. An underlying ETA seeks 90 days of authority. SUPPORTING SHIPPER(S): Walled Lake Door Company, P.O. Box 32458, 4527 N. 16th Street, Phoenix, AZ. 85064. SEND PROTESTS TO: Andrew V. Baylor DS, ICC, Room 2020 Federal Bldg., 230 N. First Avenue, Phoenix, AZ. 85025.

MC 144888 (Sub-4TA), filed November 2, 1978. Applicant: BIL-RIC TRANSPORT SYSTEMS, INC., 92 East Main Street, Somerville, NJ 08876. Representative: Joseph F. Hoary, 121 South Main Street, Taylor, PA 18517. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Such commodities* as are manufactured, sold and distributed by Beecham Products, (except commodities in bulk and foodstuffs), from the facilities of Beecham Products Company at Aiken, South Carolina, to Mechanicsburg, PA; Morrisville (Bucks County), PA; Rockwood, MI; Chicago, IL; Kansas City, MO; Memphis, TN; Savannah, GA; Los Angeles, CA and Denver, CO., under a continuing contract or contracts, with Beecham Products Company, for 150 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Beecham Products Company, P.O. Box 1467, Pittsburgh, PA, 15230. SEND PROTESTS TO: Robert E. Johnston DS, ICC, 9 Clinton Street, Newark, NJ. 07102.

MC 145243 (Sub-2TA), filed November 3, 1978. Applicant: REDBIRD DEVELOPMENT, INC., 1018 Whitlock Rd., Rochester, NY 14609. Representative: S. Michael Richards/Raymond A. Richards, P.O. Box 225, Webster, NY 14580. Authority sought to operate as a *contract carrier* by motor vehicle, over irregular routes, transporting: *Scrap metal*, from Rochester, NY to Pittsburgh, PA, under continuing contract or contracts with Lyell Metal Co., Inc., of Rochester, NY, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper: Lyell Metal Co., Inc., 1510 Lyell Ave., Rochester, NY, 14606. Send protests to: District Supervisor, I.C.C., U.S. Courthouse & Federal Bldg., 100 S. Clinton St., Rm. 1259, Syracuse, NY 13260.

MC 145406 (Sub-3TA), filed November 2, 1978. Applicant: MIDWEST EXPRESS, INC., 380 E. Fourth Street, Dubuque, IA 52001. Representative: Richard A. Westley, 4506 Regent Street Madison, WI 53705. *Natural cheeses, cheese products and cheese packaging materials*, (1) from Hyde Park, UT to points in AZ, CA, CO, ID, MT, NV, NM, OR, TX, and WA; and (2) from IA, MN, and WI to Hyde Park, UT., restricted to traffic originating at or destined to the facilities of Mountain Farms, Inc., at Hyde Park, UT., for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Mountain Farms, Inc., P.O. Box 376, 3663 N. Highway 91, Hyde Park, UT. 84318. SEND PROTESTS TO: Herbert W. Allen DS, ICC, 518 Federal Bldg., Des Moines, IA. 50309.

MC 145505 (Sub-2TA), filed November 3, 1978. Applicant: CYRIL IRISH, d/b/a SHAMROCK TRANSPORTERS, 8007 South Meridian Street, Indianapolis, IN 46227. Representative: Warren C. Moberly or Robert B. Hebert, 320 N. Meridian Street, No. 777, Indianapolis, IN 46204. *Motor vehicles*, over ¾ ton gross weight, in secondary drive-away movement, (except for automobiles, truck mounted and self-propelled cranes, and self-propelled mine, well and quarry drilling equipment), between points in Lawrence, Wayne, and Marion Counties, IN and Allen County, OH, on the one hand, and all points in the United States, (except IN, OH, AK, and HI on the other hand, for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): There are approximately (5) statements of support attached to this 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: Beverly J. Williams Trans. Asst., ICC, Federal Building, & U.S. Courthouse, 46 East Street, Room 429, Indianapolis, IN 46204.

MC 145516TA, filed November 7, 1978. Applicant: T. G. STEGALL TRUCKING CO., INC., 6333 Idlewild Road, Charlotte, NC 28212. Representative: T. G. Stegall, Jr. (same as above). *Bananas*, requiring the use of mechanically refrigerated trailers, from Charleston, SC to Charlotte, NC and Raleigh, NC for 180 days. An underlying ETA seeks 90 days authority. Supporting shippers: A & P Tea Company National Produce Division, P.O. 700, Elmwood City, NJ 07407—Associated Grocers Mutual of Carolina, Inc. 701 Lawton Road, Charlotte, NC 28237—Winn Dixie Charlotte, Inc., 1105 Nevada Blvd., Charlotte, NC 28234. Send protests to: Terrell Price,

ICC, Room CC-516, Mort Office Building, 800 Briar Creek Road, Charlotte, NC 28205.

MC 145549 (Sub-1TA), filed October 30, 1978. Applicant: STEVE ALLEN, d/b/a RIGGS & ALLEN TRANSPORTATION, 621 Harbor Boulevard, West Sacramento, CA 95691. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Lumber, wood pulp and wood products*, (including flakeboard), from the plants and facilities of Louisiana-Pacific Corporation in Humboldt County, CA, to rail reload operations located at their plants and facilities in Mendocino and Sonoma Counties, CA, under a continuing contract, or contracts, with Louisiana-Pacific Corporation, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Louisiana-Pacific Corporation, P.O. Box 158, Samoa, CA, 95564. Send protests to: A. J. Rodriguez DS, 211 Main Street, Suite 500, San Francisco, CA 94105.

MC 145707TA, filed November 3, 1978. Applicant: HENRY JOHNSON TRUCKING, 7701 Greenleaf Drive, Omaha, NE 68128. Representative: Melvin C. Hansen, 610 Service Life Bldg., Omaha, NE 68102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Meats*, from Omaha, Lyons, Crete, Schuyler and Madison, NE; Sioux City, Glenwood, Estherville, Storm Lake, Leslie, Cherokee, Denison, Iowa Falls, Des Moines, Marshalls town, Ottumwa, Davenport, Cedar Rapids, and Perry, IA; and Chicago, IL; to Sacramento and San Francisco and their commercial zones, CA, under a continuing contract, or contracts, with Pacific Provisions, Inc., for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Joseph D. Ryan, Vice President, Pacific Provisions, Inc., 139 Mitchell Avenue, Suite 219, South San Francisco, CA 94080. Send protests to: Carroll Russell DS, ICC, Suite 620, 110 North 14th Street, Omaha, NE 68102.

MC 145707 (Sub-1TA), filed November 3, 1978. Applicant: HENRY JOHNSON TRUCKING, 7701 Greenleaf Drive, Omaha, NE 68128. Representative: Melvin C. Hansen, 610 Service Life Bldg., Omaha, NE 68102. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Paper labels*, from Fort Dearborn Lithograph Company at Niles, IL, to points in CA, under a continuing contract or contracts, with Fort Dearborn Lithograph Company, for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Clifford T. Crestodina, Label Operations Manager, Fort Dearborn Lithograph Com-

pany, 6035 West Gross Point Road, Chicago, IL 60648. Send protests to: Carroll Russell DS, ICC, Suite 620, 110 North 14th Street, Omaha, NE 68102.

MC 145709TA, filed November 7, 1978. Applicant: RICKY L. CHRISTY, 809 F. Avenue, Vinton, IA 52349. Representative: Richard D. Howe, 600 Hubbell Building, Des Moines, IA 50309. *Rough cut lumber*, from the facilities of Big Timber, Inc., at or near Vinton, IA to points in IL, WI, MN and NE, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Big Timber, Inc., R. No. 2, Box 169-1, Vinton, IA 52349. Send protests to: Herbert W. Allen, ICC, 518 Federal Building, Des Moines, IA 50309.

MC 145719TA, filed October 30, 1978. Applicant: A & A TRANSPORT SERVICES, INC., Maple Tree Industrial Park, P.O. Box 12, Boston Road, Palmer, MA 01069. Representative: Arlyn L. Westergren, 7101 Mercy Road, Suite 106, Omaha, NE 68106. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Lighting fixtures and such commodities* as are used in the manufacture and production of lighting fixtures, between Wilmington, MA, on the one hand, and, on the other, points in the United States, (except Alaska and Hawaii), under a continuing contract, or contracts, with Keene Corporation, for 180 days. An underlying ETA seeks up to 90 days authority. Supporting shipper(s): Keene Corp., Industrial Way, Wilmington, MA 01887. Send protests to: David M. Miller DS, 436 Dwight Street, Room 338, Springfield, MA 01103.

MC 145722TA, filed November 3, 1978. Applicant: REM LEASING, INC., 114 Roral Road, Jamestown, NC 27282. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 Fifteenth Street, N.W., Washington, D.C. 20005. *Fabrics*, from High Point, Burlington, Concord, and Shelby, NC; Lyman and Rock Hill, SC; and Atlanta, GA; to Atlanta, GA; Tulsa, OK; and Los Angeles, CA; and *Materials, equipment, and supplies* used in the distribution and sale of fabrics, from Los Angeles, CA; and Tulsa, OK; to Tulsa, OK; and Atlanta, GA, for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Fabricut, Inc., 9303 East 46th Street, Tulsa, OK 74145. Send protests to: Archie W. Andrews DS, ICC, 624 Federal Bldg., 310 New Bern Avenue, P.O. Box 26896, Raleigh, NC 27611.

MC 145723TA, filed November 2, 1978. Applicant: H&M TRUCKING CO., Box 173, Clinton, IL 61727. Representative: Robert T. Lawley, 300 Reisch Building, Springfield, IL 62701. Authority sought to operate as a *con-*

tract carrier, by motor vehicle, over irregular routes, transporting: (1) *Soybean meal and soybean flakes*, in bulk, from Bloomington, IL to Montgomery, AL; Gainesville, Macon and Union City, GA; KY, Lansing, MI, Jackson, MI, Charlotte, NC, Cincinnati and Circleville, OH, Memphis and Nashville, TN, for the account of Ralston Purina Company, and (2) *Meat and bone meal, meat scraps, blood meal*, in bulk, from points in CO, IL, IA, IN, KY, KS, MI, MO, MN, NE, ND, OK, TX and WI to points in AR, IL, IN, IA, LA, MO, MS, OK, for the account of Agri-Trading Corporation, under a continuing contract or contracts with Ralston Purina Company and Agri-Trading Corp., for 180 days. An underlying ETA seeks 90 days authority. Supporting shipper(s): Ralston Purina Company, 835 So. 8th Street, St. Louis, MO 63188. Agri-Trading Corporation, P.O. Box 457, Hutchinson, MN 55350. Send protests to: Charles D. Little, ICC, 414 Leland Office Building, 527 East Capitol Avenue, Springfield, IL 62701.

MC 145754TA, filed November 3, 1978. Applicant's Name: SUMMIT TRANSPORTATION COMPANY, P.O. Box 1937, Breckenridge, CO 80424. Representative: John T. Wirth, 717-17th Street, Suite 2600, Denver, CO 80202. Authority sought to operate as a *contract carrier*, by motor vehicle, over irregular routes, transporting: *Yogurt and ice cream* from the facilities of Mountain High, Inc., at or near Denver and Boulder, CO, to points in the commercial zones of Phoenix, AZ; Los Angeles and San Francisco, CA; Chicago, IL; Manhattan, KS; Boston, MA; Detroit and Grand Rapids, MI; Omaha, NE; Fargo, ND; Cleveland, OH; Salt Lake City, UT; and Seattle, WA, under a continuing contract or contracts with Mountain High Incorporated, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Mountain High Incorporated, 2201 Arapahoe Street, Denver, CO 80205. SEND PROTESTS TO: Roger L. Muchanan, ICC, 492 U.S. Customs House, 721 19th Street, Denver, CO 80202.

MC 106207 (Sub-14TA), filed October 20, 1978. Applicant: NEW YORK-KEANSBURG-LONG BRANCH BUS CO., INC., 50 Highway 36, Leonardo, NJ 07737. Representative: Sidney J. Leshin, 575 Madison Avenue, New York, NY 10022. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers and their baggage*, in the same vehicle with passengers, between Pt. Pleasant, NJ and New York, NY: From Pt. Pleasant, NJ at Atlantic Avenue to Highway 35; on Highway 35 to Highway 71; on Highway 71 to Washington Boulevard, Sea Girt, NJ; on Washington Avenue to The Cres-

cent; on The Crescent to First Avenue; on First Avenue to Lake Avenue in Spring Lake, NJ; on Lake Avenue to Third Avenue; on Third Avenue to Ludlow Avenue; on Ludlow Avenue to Allaire Road to the intersection of Highway 34; on Highway 34 to the interchange 98 on the Garden State Parkway; on the Garden State Parkway to the New Jersey Turnpike; on the New Jersey Turnpike to the Pulaski Skyway; on the Pulaski Skyway to the Holland Tunnel; across the Hudson River to the Borough of Manhattan, N.Y., NY and return over the same route, for 180 days. Service is authorized to and from all intermediate stops. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): Various individuals support this application. SEND PROTESTS TO: John P. Lynn, ICC, 428 East State Street, Room 204, Trenton, NJ 08608.

MC 145040 (Sub-1TA), filed November 2, 1978. Applicant: HILTON T. RAMSEY, d/b/a RAMSEY'S BUS LINES, P.O. Box 667, Jonesboro, LA 71251. Representative: Harold R. Ainsworth, 2307 American Bank Bldg., New Orleans, LA 70130. Authority sought to operate as a *common carrier*, by motor vehicle, over regular routes, transporting: *Passengers and their baggage and express and newspapers* in the same vehicle with passengers in regular route operations, and passengers and their baggage in one-way and round trip charter operations, (1) From Monroe, LA., to Jonesboro, LA., and return via Highway I-20 to its junction with Louisiana Highway 34, thence over Louisiana Highway 34 to Chatham, LA., thence over Louisiana Highway 4 to Jonesboro, LA. (2) From Jonesboro, LA., to Winnfield, LA., and return over U.S. Hwy 167. (3) From Jonesboro, LA., to Elm Grove, LA., and return, via Louisiana Highway 4 to Ringgold, LA., thence over Louisiana Highway 154 to Elm Grove, LA. (4) From Elm Grove, LA., to Shreveport, LA., and return, via U.S. Highway 71. (Restricted against charter rights) (5) From Shreveport, LA., over U.S. Hwy 80 to the intersection of U.S. Hwy 80 and Louisiana Highway 164 and return. (Restricted against charter rights) (6) From Fillmore, LA., to Haughton LA., and return via Louisiana Highway 157. (7) From Haughton, LA., to junction of Louisiana Highway 614 and Louisiana Highway 164 and return, via Louisiana Highway 614. (8) From junction of U.S. Hwy 80 and Louisiana Highway 164 to Sibley, LA., and return via Louisiana Highway 164. (9) From Ringgold, LA., to the Louisiana-Arkansas State Line and return, via Louisiana Highway 7 to Minden, LA., thence over U.S. Hwy 80 to Dixie Inn, LA., thence over Louisiana Highway 7 to the Louisiana-Arkansas State

Line.; and (10) From the Louisiana-Arkansas State Line to Magnolia, AR., and return, via Arkansas Highway 132, for 180 days. An underlying ETA seeks 90 days authority. SUPPORTING SHIPPER(S): There are approximately (11) statements of support attached to this 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 PROTESTS TO: Connie A. Guillory DS, ICC, T-9038 U.S. Postal Service Bldg., 701 Loyola Ave. New Orleans, LA 70113.

By the Commission.

H. G. HOMME, Jr.,
Acting Secretary.

[FR Doc. 78-35681 Filed 12-21-78; 8:45 am]

[7035-01-M]

[Finance Docket No. 28841 (Sub-No. 1)]

SEABOARD COAST LINE INDUSTRIES AND SEABOARD COAST LINE RAILROAD CO.

Lease—Central Railroad Company of South Carolina Between Lane and Sumter in Williamsburg and Sumter Counties, SC

SEABOARD COAST LINE INDUSTRIES (SCLI) AND SEABOARD COAST LINE RAILROAD COMPANY (SCL), 500 Water Street, Jacksonville, FL 32202, represented by Neill W. McArthur, Jr., Assistant General Attorney, 500 Water Street, Jacksonville, FL 32202, hereby give notice that on the 17th day of November, 1978, they jointly filed with the Interstate Commerce Commission at Washington, D.C., an application under Section 5(2) of the Interstate Commerce Act for a decision seeking authority to renew and extend the existing lease of the CENTRAL RAILROAD COMPANY OF SOUTH CAROLINA (Central) for an additional term of ninety-nine (99) years. The application substantially complies with Commission applicable regulations (as clarified in Finance Docket No. 28841, decided December 13, 1978) and is hereby accepted.

The nature of the proposed transaction is a lease renewal and extension, which if authorized, will allow SCLI and SCL to continue leasing Central for an additional term of ninety-nine (99) years. Applicant SCL presently leases Central pursuant to a lease effective December 1, 1881.

The proposed lease extension will apply to the line of railroad between Lane, in Williamsburg County, SC, and Sumter, in Sumter County, SC. Presently SCL has a local freight operating in each direction daily, except Sunday. This train is Number 558, Charleston Sumter, turning back the

same day as Number 557, Sumter to Charleston. In addition to that local service, SCL operates unit coal trains over the line enroute to Pinopolis Junction, SC, and of course, the empty hopper trains return in the reverse direction. The proposed transaction, of renewing and extending the existing lease, will not make any changes in this existing operation. There is no passenger service involved in the proposed transaction.

In the opinion of the Applicants, the granting of the authority sought will not constitute a major Federal action significantly affecting the quality of the human environment within the meaning of the National Environmental Policy Act of 1969. In accordance with the Commission's Regulations (49 C.F.R. 1108.8) in Ex Parte No. 55 (Sub-No. 4), *Implementation—National Environmental Policy Act, 1969*, 352 I.C.C. 451 (1976), any protests may include a statement indicating the presence or absence of any effect of the requested Commission action on the quality of the human environment. If any such effect is alleged to be present, the statement shall indicate with specific data the exact nature and degree of the anticipated impact. See *Implementation—National Environmental Policy Act, 1969*, *supra*, at p. 487.

Interested persons may participate formally in a proceeding by submitting written comments regarding the application. Such submissions shall indicate the proceeding designation Finance Docket No. 28841 (Sub-No. 1) and the original and two copies thereof shall be filed with the Secretary, Interstate Commerce Commission, Washington, D.C. 20423, not later than 45 days after the date notice of the filing of the application is published in the FEDERAL REGISTER. Such written comments shall include the following: the person's position, e.g., party protestant or party in support, regarding the proposed transaction; specific reasons why approval would or would not be in the public interest; and a request for oral hearing if one is desired. Additionally, interested persons who do not intend to formally participate in a proceeding but who desire to comment thereon, may file such statements and information as they may desire, subject to the filing and service requirements specified herein. Persons submitting written comments to the Commission shall, at the same time, serve copies of such written comments upon the applicant, the Secretary of Transportation and the Attorney General.

H. G. HOMME, Jr.
Acting Secretary.

[FR Doc. 78-35677 Filed 12-21-78; 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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[6351-01-M]

1

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 10 a.m., January 9, 1979.

PLACE: 2033 K Street NW., Washington, D.C., 5th floor hearing room.

STATUS: Open.

MATTERS TO BE CONSIDERED: Proposed §912 Publication of Violations (requirement of exchanges to make public their findings and reasons whenever disciplinary actions are taken.).

CONTACT PERSON FOR MORE INFORMATION:

Jane Stuckey, 254-6314

[S-2582-78 Filed 12-20-78; 3:21 pm]

[6712-01-M]

2

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9 a.m., Thursday, December 21, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

MATTERS TO BE CONSIDERED:

Agenda, item No., and subject

Hearing—1—Court remand of the proceeding involving three applicants for additional frequencies in the DPLMRS (Docket Nos. 20084-200-86).

Hearing—2—Petition for extension of emergency pre-grant authority in the proceeding for construction permits in the Rural Radio Service in the applicant's certificated area in Western Utah, (CC Docket No. 78-240).

General—1—Petitions for special relief filed by Citizens Communications Center requesting approval of reimbursement provisions contained in certain licensee-citizens group agreements.

General—2—Application for Review of Staff ruling which partially denied the Freedom of Information Act request filed by Rob Warden, (FOIA Control No. 8-123).

General—3—Renewal of the Advisory Committee for Cable Signal Leakage and the Radio Technical Commission for Marine Services as Federal Advisory Committees.

General—4—First report and order, Docket 20817 amending part 13 of the rules to modify radio operator requirements and delineate operator responsibility.

Safety and special radio services—1—License assignment plans—land mobile trunked systems at 800 MHz, et al.

Safety and special radio services—2—Application filed by the Commonwealth of Puerto Rico for review of the action of the staff granting licenses to nine private hospitals in San Juan, Puerto Rico.

Common Carrier—1—A.T. & T.'s petition for reconsideration of the DDS order, 67 FCC 2d 1195 (1978), in which the Commission rejected A.T. & T.'s tariff revisions for dataphone digital service.

Common Carrier—2—A.T. & T.'s petition for reconsideration of our series 7000 rejection order.

Common Carrier—3—Petition for partial reconsideration of Commission order designation inquiry into alleged improper activities by Southern and Southwest Bell Telephone Co.

Common Carrier—4—Petition for partial reconsideration filed by A.T. & T. in response to a Commission order concerning a request for declaratory ruling by the Associated Press.

Common Carrier—5—Applications by Comsat General Corp., ITT World Communications, Inc., RCA Global Communications, Inc., and Western Union International, Inc. requesting various authorizations to extend or expand the services presently authorized to be provided over the Marisat Maritime Satellite System.

Common Carrier—6—A.T. & T. application for review, retiming for ratemaking purposes of changes in accounting treatment of plant under construction and interest during construction order in Docket No. 19129.

Common Carrier—7—Revisions to MCI tariff FCC No. 1, transmittal Nos. 86, 88, and 90.

Common Carrier—8—Telocator Network of America v. Illinois Bell Telephone Co., (File No. 20115-CD-P(-)-76).

Common Carrier—9—Application to construct Caribbean cable.

Common Carrier—10—Application of International Tele-Communications Development Corp. to land and operate one submarine cable on the island of Guam. (File No. S-C-L-50).

Common Carrier—11—Petition to require A.T. & T. to submit information regarding plans for use of its domestic satellite for specialize services; and establishment of domestic communications satellite facilities by non-government entities.

Common Carrier—12—Modification of depreciation rates for C. & P. of Virginia and New England Telephone Co.

Cable television—Request for waiver filed by WTTV, Bloomington, Ind.

Cable television—2—Petition for special relief filed by Tele-Vue Systems, Inc., Pittsburg, West Pittsburg, and Antioch, Calif.

Cable television—3—Review of the decision in Midcontinent Cable Systems Co., Webster, S. Dak.

Cable television—4—Petition for waiver filed by Midwest Video Corp., Poplar Bluff, Mo.

Cable television—5—Petition for reconsideration filed by Citizens Committee for Expansion of Commercial Television to the State of Delaware.

Assignment and transfer—1—Application (BTC-780721ID) for transfer of United Artists Broadcasting, (WRIK-TV, Ponce, Puerto Rico from the United Artists Corp. to Tele-Luz Washington, Inc.

Assignment and transfer—2—Tax certificates in connection with the sale of WAWA, West Allis, Wis. and WAWA-FM, Milwaukee, Wis. from Suburbanair, Inc. to APB Enterprises, Inc. and of WBRB-FM, Mt. Clemens, Mich. from Malrite Broadcasting Co. to Inner City Broadcasting Corp. of Michigan.

Renewal—1—Application for renewal of WTRA, Latrobe, Pa.

Renewal—2—Petitions to deny, filed by Committee for Community Access against renewal of WACQ(AM) and WTTK(FM), Boston, Mass.

Renewal—3—By direction letters imposing appropriate EEO sanctions on certain broadcast stations.

Renewal—4—Petition for reconsideration of renewal of KWAC, Bakersfield, Calif., filed by the Community Service Organization and the United Farm Workers Organizing Committee.

Aural—1—Application for FM station BPH-9566 filed by Amherst Broadcasting, Amherst, Mass.

Aural—2—Application for KEDA, San Antonio, Tex. filed by D. & E. Broadcasting Co. (ARN 780728AT).

Television—Applications of Commercial Radio Institute, Inc. (BPCT-4925) and Christian Voice of Central Ohio (BPCT-4955) for a new station on Channel 28, Columbus, Ohio.

Television—2—Application (BPCT-4878) of Sarasota-Bradenton, Florida TV, (WXLTV), Sarasota, Fla.

Television—3—Request of Bethel Broadcasting, Inc. (KYUK-TV, Bethel, Alaska) for extension of Commission's action waiving section 73.621 of the rules to allow ETV station to carry commercial matter during Alaska satellite demonstration project, and opposition to the request filed by Alaska Cable Television Association.

Broadcast—1—Declaratory ruling sought by Storer Broadcasting Co. concerning its proposed minority ownership assistance program.

Broadcast—2—Petition for reconsideration of second report and order in Docket No. 20735, changes in the rules relating to noncommercial educational FM broadcast stations.

Complaints and compliance—Response of KCCT, Inc. (KCCT), Corpus Christi, Tex., to a notice of apparent liability.

Complaints and compliance—2—Request for a declaratory ruling concerning the meaning of the phrase "program of any part thereof" in section 325(a) of the act.

This meeting may be continued the following work day to allow the Commission to complete appropriate action.

Additional information concerning the meeting may be obtained from the FCC Public Information Office, telephone 202-632-7260.

Issued: December 18, 1978.

[S-2577-78 Filed 12-20-78; 3:12 pm]

[6712-01-M]

3

FEDERAL COMMUNICATIONS COMMISSION.

TIME AND DATE: 9 a.m., Thursday, December 21, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Open Commission meeting.

CHANGES IN THE MEETING: Additional item to be considered:

Agenda, item No., and subject

Broadcast—3—First report and order in Docket No. 21474 concerning broadcast equal employment opportunity rules and forms as they apply to minorities and women.

Additional information concerning the meeting may be obtained from the FCC Public Information Office, telephone 202-632-7260.

Issued: December 19, 1978.

[S-2578-78 Filed 12-20-78; 3:12 pm]

[6712-01-M]

4

FEDERAL COMMUNICATIONS COMMISSION.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 9 a.m., Thursday, December 21, 1978.

PLACE: Room 856, 1919 M Street NW., Washington, D.C.

STATUS: Closed Commission meeting following the open meeting.

CHANGES IN THE MEETING: The following item has been deleted:

Agenda, item No., and subject

Complaints and compliance—1—Field investigation into the operation of radio stations WDAS and WDAS-FM, Philadelphia, Pa., licensed to Max M. Leon, Inc.

Additional information concerning this meeting may be obtained from the FCC Public Information Office, telephone 202-632-7260.

Issued: December 19, 1978.

[S-2579-78 Filed 12-20-78; 3:12 pm]

[6714-01-M]

5

FEDERAL DEPOSIT INSURANCE CORPORATION.

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at 4 p.m. on Wednesday, December 13, 1978, the Board of Directors of the Federal Deposit Insurance Corporation met in room 6006 of the FDIC Building, 550 17th Street NW., Washington, D.C., to approve a recommendation regarding the liquidation of assets acquired by the Corporation from United States National Bank (in receivership), San Diego, Calif.

In calling the meeting, the Board determined, on motion of Director William M. Isaac (appointive), seconded by Acting Chairman John G. Heilmann, that Corporation business required its consideration of the recommendation on less than 7 days notice to the public; that no earlier notice of the meeting was practicable; and that the meeting could be closed to public observation pursuant to subsections (c)(4), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(4), (c)(9)(B), and (c)(10)), since the public interest did not require consideration of the recommendation in a meeting open to public observation.

Dated: December 13, 1978.

FEDERAL DEPOSIT INSURANCE CORPORATION,
ALAN R. MILLER,
Executive Secretary.

[S-2573-78 Filed 12-20-78; 11:51 am]

[6714-01-M]

6

FEDERAL DEPOSIT INSURANCE CORPORATION.

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at 4:05 p.m. on Friday, December 15, 1978, the Board of Directors of the Federal Deposit Insurance Corporation met by telephone conference call to issue a temporary cease-and-desist order and to institute cease-and-desist proceedings, in accordance with sections 8(b) and 8(c) of the Federal Deposit Insurance Act (12 U.S.C. 1818(b), 1818(c)), against an insured State nonmember bank.

In calling the meeting, the Board determined, on motion of Director William M. Isaac (appointive), seconded by Acting Chairman John G. Heilmann, that Corporation business required its consideration of the matter on less than 7 days notice to the public; that no earlier notice of the meeting was practicable; and that the meeting could be closed to public observation pursuant to subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), and (c)(9)(A)(ii)), since the public interest did not require consideration of the matter in a meeting open to public observation.

Dated: December 15, 1978.

FEDERAL DEPOSIT INSURANCE CORPORATION,
ALAN R. MILLER,
Executive Secretary.

[S-2574-78 Filed 12-20-78; 11:51 am]

[6714-01-M]

7

FEDERAL DEPOSIT INSURANCE CORPORATION.

Pursuant to the provisions of subsection (e)(2) of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at 3:20 p.m. on Saturday, December 16, 1978, the Board of Directors of the Federal Deposit Insurance Corporation met by telephone conference call to (1) accept sealed bids for the purchase of certain assets of and the assumption of the deposit liabilities of North Point State Bank, Arlington Heights, Ill., which was closed by the Illinois Commissioner of Banks and Trust Co. as of the close of business December 16, 1978; (2) approve a resulting application from the Bank & Trust Co. of Arlington Heights, Arlington Heights, Ill., for consent to purchase certain assets of and assume the liability to pay de-

posits made in the closed bank and to operate the sole office of the closed bank as a facility of the Bank & Trust Co. of Arlington Heights; (3) provide such financial assistance, pursuant to section 13(e) of the Federal Deposit Insurance Act (12 U.S.C. 1823(e)), as was necessary to effect the purchase and assumption transaction; and (4) appoint a liquidator for such of the assets of the closed bank as were not purchased by the Bank & Trust Co. of Arlington Heights.

In calling the meeting, the Board determined, on motion of Director William M. Isaac (appointive), seconded by Mr. H. Joe Selby, acting in the place and stead of Acting Chairman John G. Heimann, that Corporation business required its consideration of the matter on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; and that the meeting could be closed to public observation pursuant to subsections (c)(8) and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8) and (c)(9)(A)(ii)), since the public interest did not require consideration of the matter in a meeting open to public observation.

Dated: December 18, 1978.

FEDERAL DEPOSIT INSURANCE
CORPORATION,
ALAN R. MILLER,
Executive Secretary.

[S-2575-78 Filed 12-20-78; 11:51 am]

[6740-02-M]

8

FEDERAL ENERGY REGULATORY COMMISSION.

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: Published December 18, 1978, 43 FR 58895.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., December 20, 1978.

CHANGES IN THE MEETING: The following items have been added:

Item No., docket No. and company

- CI-3. RI76-129, Byron Oil Industries, Inc.
- CP-10. RP76-3, Inland Gas Co.
- CP-11. RP72-99, Transcontinental Gas Pipe Line Corp.
- CAM-7. ERA's proposed rulemaking: Amendment to the Mandatory Petroleum Price Regulations allowing pass-through of increased rentals and the cost of vapor recovery systems above the present 3 cent-per-gallon maximum.
- CAM-8. ERA's proposed rulemaking regarding special set-aside procedures for middle distillates.
- CAM-9. FEA's proposed regulation establishing procedures for distributing refunds obtained through compliance actions to classes of unidentified purchasers.

M-7. RM79-4, amendments to the Commission's Regulations relating to independent producer filing requirements.

CI-4. CI78-1223, Laclede Gas Co.

CI-5(A). CI79-100, Galilee Land & Cattle Co.

CP-9(B). CP77-216, et al., Distrigas of Massachusetts Corp., et al.

CP-12. RP72-6 and RP76-38, et al., El Paso Natural Gas Co.

CP-13. CP71-68, et al., Columbia LNG Corp., Consolidated System LNG Corp., and Southern Energy Co.

ER-15. E-7796 and E-7777 (phase II), Pacific Gas & Electric Co.

KENNETH F. PLUMB,
Secretary.

[S-2580-78 Filed 12-20-78; 3:12 pm]

[6730-01-M]

9

FEDERAL MARITIME COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: December 18, 1978, 43 F.R. 58896.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10 a.m., December 21, 1978.

CHANGES IN THE MEETING: Addition of the following items to the open session:

- 10. Agreement No. 93-18: Modification of the North Europe-U.S. Pacific Freight Conference Agreement to extend authority on voting and independent action.
- 11. Proposed rulemaking to implement the Outer Continental Shelf Lands Act Amendments of 1978.

[S-2576-78 Filed 12-20-78; 11:51 am]

[7527-01-M]

10

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE.

TIME: 10:00 a.m.—4:00 p.m.

DATE: January 6, 1979.

PLACE: Sheraton Park Hotel, Washington, D.C.

STATUS: Closed.

MATTERS TO BE DISCUSSED: Executive Session (closed meeting, § 1703.202 (2) and (6) of the Code of Federal Regulations, 45 CFR, Part 1703).

CONTACT PERSON FOR MORE INFORMATION:

Alphonse F. Trezza, Executive Director, NCLIA, 202-653-6252.

DATED: December 18, 1978.

ALPHONSE F. TREZZA,
Executive Director, NCLIS.

[S-2581-78 Filed 12-20-78; 3:12 pm]

[4110-39-M]

11

NATIONAL COUNCIL ON EDUCATIONAL RESEARCH.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: S-1548-78, filed July 26, 1978, 11:44 a.m.

The National Council on Educational Research hereby gives notice that it has cancelled its January 11-12, 1979 meeting. The meeting has tentatively been re-scheduled for February 2-3, 1979. The agenda for this meeting and location will be published in the FEDERAL REGISTER at a later date.

PERSON TO CONTACT FOR INFORMATION:

Ella L. Jones, Administrative Coordinator, 202-254-7900.

PETER H. GERBER,
Chief, Policy and Administrative Coordination, National Council on Educational Research.

[S-2571-78 Filed 12-20-78; 11:51 am]

[7600-01-M]

12

OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 43 FR 58256, December 13, 1978.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 1 p.m. on December 21, 1978.

CHANGES IN THE MEETING: This meeting will take place at 9:30 a.m. on December 21, 1978.

[S-2570-78 Filed 12-20-78; 11:51 am]

[4410-01-M]

13

U.S. PAROLE COMMISSION—NATIONAL COMMISSIONERS (The Commissioners presently maintaining offices at Washington, D.C. Headquarters.)

TIME AND DATE: 9:30 a.m., December 20, 1978.

PLACE: Room 500, 320 First Street NW., Washington, D.C.

STATUS: Open or closed pursuant to a vote to be taken at the beginning of the meeting.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: December 7, 1978, 43 FR No. 236, pp. 57421-47467.

CHANGES IN THE MEETING: On December 19, 1978, the Commission

determined that the date and time for the above meeting be changed to Wednesday, December 27, 1978, at 9:30 a.m., that the place be changed to Room 831, 320 First Street NW., Washington, D.C.; and that the above change be announced at the earliest practicable time.

CONTACT PERSON FOR MORE INFORMATION:

A. Ronald Peterson, Analyst, 202-724-3094.

[S-2572-78 Filed 12-20-78; 11:51 am]

Registered
Federal

FRIDAY, DECEMBER 22, 1978
PART II



DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE

Food and Drug
Administration

■

NONCLINICAL
LABORATORY STUDIES

Good Laboratory Practice
Regulations

[4110-03-M]

Title 21—Food and Drugs

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

[Docket No. 76N-0400]

NONCLINICAL LABORATORY STUDIES

Good Laboratory Practice Regulations

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The agency is issuing final regulations regarding good laboratory practice in the conduct of non-clinical laboratory studies. The action is based on investigatory findings by the agency that some studies submitted in support of the safety of regulated products have not been conducted in accord with acceptable practice, and that accordingly data from such studies have not always been of a quality and integrity to assure product safety in accord with the Federal Food, Drug, and Cosmetic Act and other applicable laws. Conformity with these rules is intended to assure the high quality of nonclinical laboratory testing required to evaluate the safety of regulated products.

EFFECTIVE DATE: June 20, 1979.

FOR FURTHER INFORMATION CONTACT:

Paul D. Lepore, Bureau of Veterinary Medicine (HFV-102), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, (301-443-4313).

SUPPLEMENTARY INFORMATION: The Food and Drug Administration (FDA) is establishing regulations in a new Part 58 (proposed as Part 3e) in Title 21 (21 CFR Part 58) regarding good laboratory practice. These constitute the first of a series of regulations concerning investigational requirements which are being developed as a result of the FDA Bioresearch Monitoring Program. Proposed regulations, providing interested persons 120 days to submit comments, were published in the FEDERAL REGISTER of November 19, 1976 (41 FR 51206). In addition, public hearings were held on February 15 and 16, 1977 for the presentation of oral testimony on the proposal. Twenty-two oral presentations were given (transcripts are on file with the Hearing Clerk, Food and Drug Administration), and 174 written comments were received. The comments have been categorized and include the fol-

lowing: manufacturers of regulated products (64), associations (40), medical centers (20), private testing or consulting laboratories (18), educational institutions (15), government agencies (8), individuals (8), and an airport director (1).

In the proposal, regulations were designated as a new Part 3e. This final rule incorporates them into a new Part 58 (21 CFR Part 58). The following redesignation table correlates the new sections with those proposed, and, in most instances, reference to the new sections will be used hereinafter.

New Section	Old Section
Subpart A	
58.1	3e.1
58.3	3e.3
58.10	3e.10
58.15	3e.15
Subpart B	
58.29	3e.29
58.31	3e.31
58.33	3e.33
58.35	3e.33
Subpart C	
58.41	3e.41
58.43	3e.43
58.45	3e.45
58.47	3e.47
58.49	3e.49
58.51	3e.51
58.53	3e.53
Subpart D	
58.61	3e.61
58.63	3e.63
Subpart E	
58.81	3e.81
58.83	3e.83
58.90	3e.90
Subpart F	
58.105	3e.105
58.107	3e.107
58.113	3e.113
Deleted	3e.115
Subpart G	
58.120	3e.120
58.130	3e.130
Subpart J	
58.185	3e.185
58.190	3e.190
58.195	3e.195
Subpart K	
58.200	3e.200
58.202	3e.202
58.204	3e.204
58.206	3e.206
58.210	3e.210
58.213	3e.213
58.215	3e.215
58.217	3e.217
58.219	3e.219

As a part of the overall bioresearch monitoring program that was described in the proposal, a pilot inspection program was carried out to assess the current status of laboratory practice of nonclinical testing facilities to aid in evaluating the relevance of the proposed regulations, and to identify any unanticipated difficulties in implementing an agency-wide monitoring and compliance program for the testing facilities.

The pilot inspection program began in December of 1976 and covered a representative sample of testing facilities. The results of these inspections have been evaluated, and the results of the analysis have been made available to the public as OPE Study 42, "Results of the Nonclinical Toxicology Laboratory Good Laboratory Practices Pilot Compliance Program." Notice of availability of this report was published in the FEDERAL REGISTER of October 28, 1977 (42 FR 56799).

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GENERAL ISSUES

1. Many of the written responses to the proposal were in two parts: a discussion of broad issues and a critique of the regulations by section and paragraph. Over a thousand individual items have been considered.

2. Thirty-two comments requested republication of the proposed regulations as guidelines.

The Commissioner of Food and Drugs advises that publishing guidelines rather than regulations was considered and rejected before publication of the proposal. The question was considered again in preparation of this order, and again rejected. The seriousness of problems encountered in testing facilities demands the use of an approach that will achieve compliance directly and promptly. Only by specifying

the requirements for compliance in detailed, enforceable regulations can the Commissioner be assured of the quality and integrity of the data submitted to the agency in support of an application for a research or marketing permit.

3. Some comments objected to the incorporation by reference of other laws, recommendations, and guidelines as being either redundant or without the authority conferred by rulemaking procedures as required by the Administrative Procedure Act. It was also asserted that such incorporation could lead to confusion.

The Commissioner agrees that these regulations should not duplicate regulations and requirements subject to the purview of other agencies. Therefore, reference to animal care provisions of the Animal Welfare Act of 1970 (Pub. L. 91-570) and recommendations contained in Department of Health, Education, and Welfare (HEW) Publication No. (NIH) 74-23 have been deleted from §§ 58.43(a) and 58.90(a) (21 CFR 58.43(a) and 58.90(a)). Also, all provisions that referred to regulations of the Occupational Safety and Health Administration or were concerned with the health and safety of employees have been revised or deleted, i.e., 21 CFR 58.33(a) (by deletion of proposed 21 CFR 3e.31(a)(11)), 21 CFR 58.53(b), 21 CFR 58.81 (by deletion of proposed 21 CFR 3e.81(b)(10)), and 21 CFR 58.120(a) (by deletion of proposed 21 CFR 3e.120(a)(17)). Reference to the regulations of the Nuclear Regulatory Commission has been removed from § 58.49; and proposed § 3e.115, dealing with the handling of carcinogenic substances, has been deleted. In addition, the Commissioner has deleted reference to the various animal care guideline cited in the proposal.

4. Some comments said the regulations should not be retroactive to previous studies or those ongoing and should include reasonable transitional provisions for their implementation.

To give nonclinical laboratory facilities adequate time to implement required changes in their organization and physical plant, a period of 180 days after publication in the FEDERAL REGISTER is provided for these regulations to become fully effective. The regulations are not retroactive. All studies initiated after the effective date shall be subject to the regulations. The remaining portions of studies in progress on the effective date of the regulations shall be conducted in accordance with these regulations.

5. A number of comments challenged the general legal authority of FDA to issue good laboratory practice regulations. Other comments challenged the legal authority to require record retention or quality assurance units, or to

specify the content of required records or location of storage.

The Commissioner finds that the authority cited in the preamble to the proposal (41 FR 51219; Nov. 19, 1976) provides a sound legal basis for the regulations. Although many matters covered in these regulations are not explicitly mentioned in any of the laws administered by the Commissioner, the Supreme Court has recognized, in *Weinberger v. Bentex Pharmaceuticals, Inc.*, 412 U.S. 645, 653 (1973), that FDA has authority that "is implicit in the regulatory scheme, not spelled out in *haec verba*" in the statute. As stated in *Morrow v. Clayton*, 326 F.2d 36, 44 (10th Cir. 1963):

However, it is a fundamental principle of administrative law that the powers of an administrative agency are not limited to those expressly granted by the statutes, but include, also, all of the powers that may be fairly implied therefrom.

See *Mourning v. Family Publications Service, Inc.*, 411 U.S. 356 (1973); see also *National Petroleum Refiners Association v. F.T.C.*, 482 F.2d 672 (D.C. Cir. 1973). The Commissioner concludes that there is ample authority for the promulgation of good laboratory practice regulations. No comment presented any explanation or information to the contrary, let alone a cogent argument that FDA lacks legal authority under existing statutes. The standards prescribed represent amplification of the legal requirements regarding evidence of safety necessary to approve an application for a research or marketing permit and parallel, to a great extent, steps that FDA has found have been taken by members of the regulated industry to improve non-clinical laboratory operations.

6. One comment argued that the opinion of the Court of Appeals in *American Pharmaceutical Association v. Weinberger*, 530 F.2d 1054 (D.C. Cir. 1976), should be read to limit FDA's authority to issue regulations under section 701(a) of the act (21 U.S.C. 371(a)).

The Commissioner disagrees with the argument advanced in the comment. As discussed in the preamble to the proposed regulation, the agency's authority to issue regulations under section 701(a) of the act has been upheld by the courts. (See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609 (1973); see also *National Confectioners Association v. Califano*, No. 76-1617 (D.C. Cir. Jan. 20, 1978); *Upjohn Co. v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Pharmaceutical Manufacturers Association v. Richardson*, 318 F. Supp. 301 (D. Del. 1970).) The question is not FDA's authority to issue regulations under section 701(a) of the act per se, but whether regulations issued under section 701(a) of the act appropriately implement other sec-

tions of the act. As articulated in the original proposal, and as discussed in the previous two paragraphs, the Commissioner has determined that these regulations are essential to enforcement of the agency's responsibilities under sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512, 513, 514, 515, 516, 518, 519, 520, 706, and 801 of the Federal Food, Drug, and Cosmetic Act, as well as the responsibilities of FDA under sections 351 and 354-360F of the Public Health Service Act.

7. A number of comments said various sections of the act did not specify the submission of safety data or did not deal with "applications for research or marketing permits."

The Commissioner has reviewed the comments and finds that the comments are based on a misunderstanding of the phrase, "applications for research or marketing permits." This concept is discussed in relation to § 58.3(e) below. Each cited provision contains authority for FDA either to require submission of, or to use, non-clinical safety data to justify a decision to approve the distribution of a regulated product.

8. A number of comments said the cost of implementing the proposed regulations would be prohibitive to smaller testing laboratories and would, at the least, result in a substantial increase in the cost of product testing.

The Commissioner agrees that implementation of these regulations will increase the cost of nonclinical laboratory testing. The Commissioner finds, however, that such costs are justified on the basis of the resultant increase in the assurance of the quality and integrity of the safety data submitted to the agency. The agency has previously concluded (see the FEDERAL REGISTER of November 19, 1976 (41 FR 51220)) that this document does not contain regulations requiring preparation of an inflation impact statement under Executive Orders 11821 and 11929, Office of Management and Budget Circular A-107 and the guidelines issued by the Department of Health, Education, and Welfare. For a notice on the availability of the agency's economic impact assessment regarding rules for good laboratory practice for nonclinical laboratory studies, see the FEDERAL REGISTER of February 7, 1978 (43 FR 5071). The revisions in this final rule, along with the findings of the pilot program, which showed that many of the inspected facilities were already substantially in compliance with the proposed regulations, should allay some of the concerns of small facilities regarding cost or feasibility of compliance.

9. Many comments suggested 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. Comments 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 editorial and stylistic and do not warrant a detailed discussion.

The Commissioner has 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 had not been previously noted by FDA. Where the proposed alternative language or other changes suggested by the comments 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.

GENERAL PROVISIONS

SCOPE

10. Numerous comments addressed the stated scope of the proposed regulations (§ 58.1). Six comments said the proposed scope was vague. Ten comments said the scope should be limited to long-term animal toxicity studies. Twenty-two comments indicated that the scope should be limited to animal safety studies to be submitted to FDA. Individual comments recommended limiting the scope to studies performed on marketed products, studies performed on animals and other biological test systems, or studies submitted in support of a color additive petition, food additive petition, investigational new drug application, new drug application, or new animal drug application.

In the preamble to the proposed regulations, the Commissioner set forth the reasons for the broad terminology employed in the statement of scope, stating "these regulations are intended to ensure, as far as possible, the quality and integrity of test data that are submitted to FDA and become the basis for regulatory decisions made by the Agency." In the proposed rule (41 FR 51210), the Commissioner specifically invited comments on which laboratories and/or studies should be subject to the regulations, and further, on whether the scope of the regulations should be defined in terms of the type of testing facility rather than the type of study performed. Based on the review of the comments, the Commissioner has chosen to describe the scope of the regulations in language

that is only slightly changed from the proposal. Further clarification of scope is achieved by the specific definition of the key terms, "nonclinical laboratory study" and "application for research or marketing permit" in § 58.3. Taken together, these provisions eliminate any vagueness in the scope of these regulations.

The Commissioner has rejected the request to narrow the scope by listing in the regulation specific types of studies covered. Any such list, if it included all types of studies used by the agency to assess the safety of all the products it regulates, would be cumbersome and might exclude specific types of studies that could become important to future safety decisions. The Commissioner emphasizes that this decision does not mean, however, that the scope of the regulations is unlimited. The scope of the GLP regulations is limited in several ways.

First, they apply only to nonclinical laboratory studies that are submitted or are conducted for submission to the agency in support of a research or marketing permit for a regulated product. Language has been added that provides that the scope includes studies "intended" to support applications for research or marketing permits. This language was included in the preamble to the proposed regulation (41 FR 51209), and the Commissioner has added the language to the regulation because it helps to make clear in advance when a study should comply with the regulation and when a study should be listed on a testing facility's master schedule sheet as a nonclinical laboratory study subject to these regulations (§ 58.35(b)(1)). Tests never intended to be submitted to the agency in support of (i.e., as the basis for) the approval of a research or marketing permit, such as exploratory safety studies and range-finding experiments, are not included even though they may be required to be submitted as part of an application or petition.

Second, the definition of "nonclinical laboratory study" (§ 58.3(d)) makes it very clear that studies utilizing human subjects, clinical studies, or field trials in animals are not included.

Third, the scope of coverage is now limited to safety studies, i.e., those which can be used to predict adverse effects of, and to establish safe use characteristics for, a regulated product. "Functionality studies" have been excluded in the final rule.

Fourth, the definition of "test system" (§ 58.3(i)) taken together with the definition of "nonclinical laboratory study" makes it clear that the scope of coverage is confined to studies performed on animals, plants, microorganisms or subparts thereof.

Products regulated by the agency, for which safety data may be required,

cover a wide range of diverse items that pose quite different types of risk. Examples include implantable medical devices; indirect food additives which may occur in food in very small quantities; direct food additives which may be consumed on a daily basis in larger quantities; human drugs intended for prescription or over-the-counter use; animal drugs intended for use in pets and other companion animals of social importance, drugs used in food-producing animals (drug residues can become a part of food); radiation products used in the diagnosis and/or treatment of a disease or condition; radiation products (e.g., microwave ovens and television sets) widely used by the public; vaccines; and blood components and derivatives.

The guarantee of the safety of each of these product classes requires conducting a broad spectrum of safety tests, all of which should be subject to the same standards. Therefore, the Commissioner rejects the proposal to limit the scope of these regulations to long-term animal toxicity studies. Median lethal dose (LD_{50}) and other short-term tests are covered by the regulations because they may serve as part of the basis for approval of, for example, use of an indirect food additive or an investigational new drug in man.

In vitro biological tests are included insofar as such tests have a bearing on product safety, even though they are not now used in agency decisions, because they may in the future become important indicators of safety. Examples of such tests include short-term mutagenicity tests as well as various other tissue culture and organ tests.

Also included in the scope of these regulations are studies of safety of regulated products on target animals, acute toxicity studies on a final product formulation, studies of test articles that are completed in 14 days or less, studies conducted on test articles used in "minor food producing species of animals," and studies on test articles which are not widely used.

11. Several comments closely related to the concerns expressed in paragraph 10 of this preamble requested that further language be added to the regulation exempting certain specific types of studies from coverage.

The Commissioner has reviewed the requests and has chosen not to change the language of the regulation itself to exclude specific study types other than those already mentioned (e.g., studies utilizing human subjects). The regulations apply to any study conducted to provide safety data in support of an application for a research or marketing permit for an FDA-regulated product, and a specific type of study which may be important in the overall safety evaluation of one type

of regulated product may not be important in evaluating another. The Commissioner believes it useful to identify in this preamble further examples of studies that are—or are not—within the scope of the GLP regulations.

Examples of studies that are not within the scope of these GLP regulations include:

- a. Clinical tests performed solely in conjunction with product efficacy.
- b. Chemical assays for quality control.
- c. Stability tests on finished dosage forms and products.
- d. Tests for conformance to pharmacopeial standards.
- e. Pharmacological and effectiveness studies.
- f. Studies to develop new methodologies for toxicology experimentation.
- g. Exploratory studies on viruses and cell biology.
- h. Studies to develop methods of synthesis, analysis, mode of action, and formulation of test articles.
- i. Studies relating to stability, identity, strength, quality, and purity of test articles and/or control articles that are covered by good manufacturing practice regulations.

Further examples of types of tests not covered include:

- a. Food additives: Tests of functionality and/or appropriateness of the product for its intended use; tests of extractability of polymeric materials that contact food; and all chemical tests used to derive the specifications of the marketed product.
- b. Human and animal drugs: Basic research; preliminary exploratory studies; pharmacology experiments; studies done to determine the physical and chemical characteristics of the test article independent of any test system; and clinical investigations.
- c. Medical devices: All studies done on products that do not come in contact with or are not implanted in man.
- d. Diagnostic products: Essentially all are excluded.
- e. Radiation products: Chemical and physical tests.
- f. Biological products: All tests conducted for the release of licensed biologicals described in Part 601 (21 CFR Part 601) of this chapter.

These examples do not represent all the exclusions from the regulations, but provide guidance in applying the agency's safety considerations to specific situations. The defined scope of the regulations is necessarily broad to encompass the wide range of types of safety tests, types of testing facilities and regulated products for which proper safety decisions are important.

12. More than 20 comments sought the addition of specific language exempting various classes of FDA-regulated products, such as medical de-

vices, from coverage by the regulations.

The Commissioner has generally elected not to permit exemptions based on broad categories of regulated products because no compelling reasons have been presented that would support the contention that assurance of safety is less desirable for one class of regulated products than for another. Proper safety decisions are important for all these products; accordingly, the processes by which such safety data are collected should be subjected to identical standards of quality and integrity.

13. Several comments said that the animal care provisions should apply only to these nonclinical studies using laboratory animals and should not apply to nonclinical studies which involve large animals.

It is clear that the animal care provisions are directed toward the use of laboratory animals, and therefore certain of these provisions may not apply to studies not involving laboratory animals, such as tissue residue and metabolism studies conducted in cattle. Although these studies do fall within the definition of a nonclinical laboratory study, the animals used in such a study are not generally kept in a laboratory setting. Because the husbandry requirements for laboratory animals differ greatly from those for large animals, the agency does not require that large animals be reared and maintained under the same conditions as laboratory animals. The regulations are revised to include terms such as "when applicable" and "as required" in those provisions for which a wide latitude of acceptable husbandry practice exists.

14. Three comments said the regulations should apply to all studies whether submitted in support of or as a challenge to an "application for a research or marketing permit."

The Commissioner agrees, in principle, that all nonclinical studies should be performed in a manner designed to ensure the quality and integrity of the data. FDA is requiring that, at the time a study is submitted, there be included with the study either a statement that the study was conducted in compliance with Part 58 requirements or, if the study was not conducted in compliance with those requirements, a statement that describes in detail all deviations. This requirement means that, at the time a study not conducted in compliance with the requirements is submitted, the agency may evaluate the effects of the noncompliance and take one of the following actions: (1) Determine that the noncompliance did not affect the validity of the study and accept it, or (2) determine that the noncompliance may have affected the validity of the study

and require that the study be validated by the person submitting it, or (3) reject the study completely. The standard of review applied to studies that contain data adverse to a product is no different. That is, a study that failed to comply with these regulations might, nonetheless, contain valid and significant data demonstrating a safety hazard. Thus, FDA is not proposing a double standard, but is, rather, seeking to address those studies that present the most serious regulatory problems.

The preamble to the proposed regulation (41 FR 51215) discussed this issue as follows:

Valid data and information in an otherwise unacceptable study which are adverse to the product, however, may serve as the basis for regulatory action.

This disparity in treatment merely reflects the fact that a technically bad study can never establish the absence of a safety risk but may establish the presence of a previously unsuspected hazard. It reflects current agency policy; even in situations where the scientific quality of an investigational drug study is not in question, FDA may receive data but not use it in support of a decision to approve testing or commercial distribution because of ethical improprieties in the conduct of the study. (See 21 CFR 312.20).

A positive finding of toxicity in the test system in a study not conducted in compliance with the good laboratory practice regulations, may provide a reasonable lower bound on the true toxicity of the substance. The agency must be free to conclude that scientifically valid results from such a study, while admittedly imprecise as to incidence or severity of the untoward effect, cannot be overlooked in arriving at a decision concerning the toxic potential of the product. The treatment of studies conducted by a disqualified testing facility is discussed in paragraph 231a, below.

15. Exemptions from coverage by these regulations were requested for various types of facilities. Requests were received that they not apply to academic, medical, clinical, and not-for-profit institutions.

The public health purpose of these regulations applies to all laboratory studies on which FDA relies in evaluating the safety of regulated products, regardless of the nature of the facilities in which the studies are conducted. The Commissioner finds that granting an exemption based on type of facility would frustrate the intent of the good laboratory practice regulations. Many other comments urged that such exemptions not be considered because the standards applied to nonclinical testing should be uniform. Many of the requests for exemption were based on the idea that academic or not-for-profit institutions conduct primarily basic research and ought,

therefore, to be specifically excluded. Insofar as academic institutions are concerned, the Commissioner notes that such institutions conduct significant amounts of commercial testing pursuant to contracts. He also notes that significant levels of noncompliance with GLP requirements have been found in such institutions. Moreover, as noted in paragraph 11, basic research on drugs is outside the scope of these regulations. In short, no justification has been presented to warrant granting an exemption to such a facility, and any such exemption from the regulations by the type of facility collecting safety data would not provide equal application of the principles of good laboratory practice. Product safety decisions are equally important whether data are collected by the largest commercial nonclinical laboratory facility or by the smallest nonprofit facility. Therefore, the data collected in all types of facilities should be subjected to the same standards of quality and integrity. The results of the pilot program show that the proposed regulations represent achievable standards.

16. Exemption of or different standards for studies conducted outside the United States were requested.

These regulations are designed to protect the public health of the American people by assuring the scientific integrity and validity of laboratory studies that the agency relies on in evaluating the safety of regulated products. The same assurance is needed, whether the studies relied on are foreign or domestic in origin. The Commissioner notes that FDA clearly may refuse to accept studies from any nonclinical testing facility, foreign or domestic, that does not follow the requirements set forth in these regulations. To exempt from the requirements imposed on studies conducted in domestic testing facilities a nonclinical study conducted in a testing facility outside the United States that is submitted to FDA in support of an application for a research or marketing permit or to impose different standards for such studies, would only have the effect of discriminating against U.S. firms. Although inspection of a foreign facility may not be made without the consent of that facility, FDA will refuse to accept any studies submitted by any facility that does not consent to inspection. These same conditions apply to other FDA regulations, e.g., the current good manufacturing practice regulations (21 CFR Part 210), a program of inspection of foreign facilities for compliance with those regulations has been conducted by FDA for several years. A similar inspection program of foreign laboratory facilities conducting studies within the scope of this regulation will

be conducted; several foreign laboratories were inspected during the pilot program, and mechanisms for such inspections are being worked out with representatives of the responsible regulatory authorities in foreign countries.

DEFINITIONS

The Commissioner received hundreds of comments regarding definitions (§ 58.3). General comments are listed immediately below; comments regarding specific definitions follow in numerical order.

17. Several comments asked that commonly used terms such as "batch," "area," "laboratory," "pathologist," "quality data," "data integrity," "supervisor," and "management" be defined or clarified.

The Commissioner finds that, with the exception of "batch," the terms set out above do not require individual definitions. The term "pathologist" is used in its ordinary sense, as are the terms "supervisor" and "management" and the phrases "quality data" and "data integrity." As a general rule, the regulation defines separately only those words which will be used in a sense which differs from that given in currently accepted dictionaries or words whose meaning will be limited by the regulation. A new definition has been added for the term "batch" because it is used in these regulations in a context different from other agency regulations, e.g., the good manufacturing practice regulations. "Batch" in these regulations means a specific quantity of a test or control article that has been characterized according to § 58.105(a).

18. Several comments on § 58.3(b) questioned the applicability of the term "test substance" to medical devices, radiation products, in vitro diagnostic products, and botanical materials.

The Commissioner has reviewed the comments carefully and finds that many of the comments submitted regarding the term "test substance" argued that the term, as defined, did not accurately reflect the scope intended to be covered. Because the term "substance," in common usage, refers to chemical compounds and biological derivatives of more or less defined composition, and because the term is not commonly understood to include devices or electronic products, the Commissioner has changed the term "test substance" to "test article." The term "article" is intended to include all regulated products which may be the subject of an application for a research or marketing permit as defined in § 58.3(e).

The Commissioner has deleted the reference to botanical materials because all botanical materials subject to

FDA jurisdiction are adequately encompassed by the other articles specifically mentioned in the definition.

19. Clarification of the term "control substance" (§ 58.3(c)) was requested. Several comments asked whether the term was to include carrier substances and solvents and vehicles. Other comments suggested this term could be confused with the same term used by the Drug Enforcement Administration.

The term is changed to "control article" to parallel the revised definition for test article. This change avoids any potential conflict with definitions used by other agencies. The term is intended to define those materials given to control groups of test systems for establishing a basis of comparison. The Commissioner recognizes that for certain nonclinical laboratory studies, no control groups are used, and therefore this definition would not apply. For example, testing the safety of implantable pacemakers in animals would require either no control animals or animals that have only been "sham-operated." The definition includes carrier materials when such carrier materials are given to control groups within test system and likewise for administered vehicles and solvents. The term also applies to articles used as positive controls.

20. Many comments on § 58.3(d) addressed the definition of the term "nonclinical laboratory study." A great many, if not the majority, of the comments sought to change the definition by adding language excluding certain specific tests, products, or types of laboratories.

The Commissioner notes that many of these comments overlap with or are identical to comments submitted in response to § 58.1 (Scope). To the extent that the comments and issues are the same, they have been dealt with in the discussion of § 58.1, above. Other comments are dealt with specifically below.

21. Many comments stated that the proposed language which included studies intended to assess the functionality and/or effectiveness of a test article should be deleted. One comment stated that efficacy testing in nonclinical tests is, by definition, preliminary and should be excluded to be consistent with the scope defined in § 58.1. Other comments stated that the language was too broad and too ambiguous and could be interpreted to include many studies which were not safety studies at all.

The Commissioner has considered these comments and agrees that the language related to functionality and/or effectiveness is too broad. He has, therefore, deleted the sentence.

22. Several comments requested that the last sentence of § 58.3(d) be modified

by deleting the proposed examples of tests.

The Commissioner finds that the examples included in the proposal tended to confuse rather than clarify. The examples, therefore, have been deleted.

23. Section 58.3(e), which defines the various types of submissions to FDA, was criticized for use of the term "application for research or marketing permit." Several comments said the term was misleading because not all products are regulated through the use of "permits."

The Commissioner believes the term is appropriate for the purpose of these regulations. As stated in the proposal, this definition includes all the various requirements for submission of scientific data and information to the agency under its regulatory jurisdiction, even though in certain cases no permission is technically required from FDA for the conduct of a proposed activity with a particular product, i.e., carrying out research or continuing marketing of a product. The term is intended solely as a shorthand way of referring to the separate categories of data (identified in the proposal) that are now, or in the near future will become, subject to requirements for submission to the agency.

24. One comment stated that proposed § 3e.3(e)(14) should be deleted because the language was overly broad and because it contradicted the intent expressed in the preamble to limit GLP regulations to safety studies.

The Commissioner notes that the preamble to the proposal (41 FR 51209) stated that studies conducted to determine whether a drug product conforms to applicable compendial and license standards were excluded from the regulation. Safety data submitted to obtain the initial licensing of a biological product are covered by these regulations in § 58.3(e)(13). Once a biological is licensed, however, it becomes subject to testing procedures similar to compendial testing procedures. The Commissioner finds that postlicensing testing of biologicals is conducted more for quality control purposes than for establishing the basic safety of the biologic product and has, accordingly, deleted postlicensing testing from the definition of research and marketing permit.

25. Several comments stated that in vitro diagnostic tests (proposed § 3e.3(e)(15)) should not be included because in vitro diagnostic products do not come in contact with patients and do not, therefore, require preliminary animal safety testing.

Because in vitro diagnostic products do not require any nonclinical laboratory tests for agency approval, the Commissioner agrees that in vitro diagnostic products need not be included

in the definition "application for a research or marketing permit." Proposed § 3e.3(e)(15) has, therefore, been deleted from the final regulation.

26. Several comments objected to the inclusion of medical devices in § 58.3(e) (16), (17), and (18), stating that medical devices were not "test substances," that medical devices should not be included because the rules for data submission for such devices were as yet undefined, and that inclusion of medical devices would be unduly restrictive. These comments suggested either total or partial exclusion from coverage under the good laboratory practice regulations.

For reasons stated previously, the Commissioner does not agree that medical devices, as a category, should be excluded. Implantable devices may be composed of polymeric materials that contain components capable of leaching from the device into the body of the recipient or may themselves be adversely affected by body constituents. In either case, safety studies would be necessary to demonstrate that components of the device did not cause harm or that the body constituents did not promote breakdown or malfunction of the device.

27. Comments also requested deletion of all terms relating to radiation products in § 58.3(e) (20), (21), and (22), stating that to include such products would restrict experimentation unduly, and arguing that radiation products were not "test substances."

The Commissioner rejects these comments. The quality and integrity of the safety data are no less important for radiation products than they are for other agency-regulated products. He does not agree that including radiation products will unduly restrict experimentation. The remaining argument is covered in the discussion of "test article" above. A new paragraph § 58.3(e)(19) is added to cover data and information regarding an electronic product submitted as part of the procedure for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation performance standard, described in Subpart D of Part 1003 (21 CFR Part 1003).

28. Many comments stated that the term "sponsor" in § 58.3(f) was too broadly defined. For example, two comments stated that the definition, as written, would cover a company which provides a grant to a university, a fact which, if true, would inhibit giving grants. One comment said that the definition is so broad that it could be interpreted to apply to stockholders.

The Commissioner advises that a person providing a grant may be a sponsor. In the area of nonclinical laboratory studies, most grantors ulti-

mately submit the data to the agency. The Commissioner does not agree that because the definition of "sponsor" includes grantors it will inhibit the giving of grants. No data were submitted to support this argument. The Commissioner further advises that the definition does not include stockholders.

29. Other comments on § 58.3(f) asked whether the regulation allowed for multiple sponsors and whether government agencies could be sponsors.

"Person," as defined in § 58.3(h), includes government agencies, partnerships, and other establishments such as associations. Therefore, a government agency can clearly be a sponsor. In addition, the Commissioner advises that the definition does not preclude joint sponsorship of a study.

30. Several comments asked that the definition of "testing facility" in § 58.3(g) be revised to indicate clearly that a facility conducting a study subject to the regulations should be subject only to the extent that the facility is involved with and responsible for the study.

The Commissioner concludes that no revision to the definition is necessary. The definition clearly does indicate that a facility is covered by the regulations only to the extent that the facility is conducting or has conducted non-clinical laboratory studies.

31. Numerous comments addressed the definition of "test system" in § 58.3(i). Eighteen comments stated that the definition, as written, could be interpreted to require testing of beakers and test tubes. Two comments pointed out that the "test system" is not the container being tested for extractables, but rather it is the animal, microorganism, or cellular components used to test the extractables for safety.

The Commissioner has carefully reviewed the proposed definition in light of the comments and has made a number of changes. The terms "cellular and subcellular" have been replaced for clarity with "subparts thereof" which refers to animals, plants, and microorganisms. The revised definition now reads: "'Test system' means any animal, plant, microorganism, or subparts thereof, to which the test or control article is administered or added for study. 'Test system' also includes appropriate groups or components of the system not treated with the test or control articles." The revisions should make the definition clearly consistent with § 58.3(d) ("nonclinical laboratory study"), which states that studies to determine physical or chemical characteristics of a test article or to determine potential utility are not included. Therefore, testing of beakers and test

tubes, which fall into the category of physical and chemical tests, is excluded.

32. Section 58.3(j), which defines "specimen," drew several comments. These included requests for precise definition of the terms "material" and "tissue" and requests for a clearer definition of the term "specimen."

The Commissioner is modifying the term "specimen" to include any material derived from a test system for examination or analysis. Under these circumstances, blood, serum, plasma, urine, tissues, and tissue fractions are all included if they are intended for further examination or analysis. The definition includes all materials that yield data related to the safety decision on a regulated product.

33. Many comments were received on the definition of "raw data" in § 58.3(k). Included were requests to clarify the term "certified" and to state whether carbons, photocopies, and written reports of dictated material could be classified as "raw data". Other issues concerned whether financial information and first drafts of reports were "raw data."

The Commissioner concludes that the proposed definition should be clarified. The word "exact" is substituted for the word "certified." "Certified" connotes a legal document that requires notarization; "exact" has no such connotation and more precisely reflects the Commissioner's intention. The definition is further clarified by inserting, after the first sentence, a new sentence which reads: "In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data." This clarification will permit data collection by tape recorders without requiring the retention of the original tapes. Carbons and photocopies satisfy the regulations, provided they are exact and legible copies of the original information. Neither financial information nor first drafts of reports are raw data within the meaning of the term.

34. Several comments said only recorded data contributing substantially to the study should be retained and, similarly, only computer printouts contributing substantially should be retained. Several comments requested clarification of the method for storing machine-generated data and definition of "on line data recording system."

Because the parenthetical example ("derived from on-line data recording systems") served more to confuse than to clarify, it has been deleted. However, an "on line data recording system" pertains to an instrument that can feed data directly into a computer

that analyzes and stores the information. The product of this activity usually consists of a memory unit plus a computer program for extracting the information from the unit. Hard-copy computer printouts are unnecessary, provided the computer memory and program are accompanied by a procedure that precludes tampering with the stored information.

The Commissioner cannot agree that only those portions of the data that contribute substantially to the study need to be retained. Such an approach would require a judgment to be made which, if in error, could lead to improper or incorrect study reconstruction. The purpose of retaining the raw data is to permit the quality assurance unit and agency investigators to reconstruct each phase of a nonclinical laboratory study. Discarding essential records would frustrate this purpose. Raw data may be stored in separate areas provided the archival indexes give the data location.

35. Many comments addressed "quality assurance unit" in § 58.3(l).

The Commissioner has reviewed these comments and concludes that they are more concerned with the concept of the quality assurance unit than with the definition. The comments are therefore dealt with in detail in that section of the preamble concerned with § 58.35 of the regulations. (See paragraphs 75 through 92 below.)

36. Several comments addressed "study director" in § 58.3(m). These comments requested clarification, permission to have more than one study director per study, and that the term "implementation" be changed to "conduct."

The Commissioner has revised the definition to read: "'Study Director' means the individual responsible for the overall conduct of a nonclinical laboratory study." The revision is intended to emphasize that the study director is responsible for the entire study, as well as being responsible for the interpretation, analysis documentation, and reporting of results.

The Commissioner concludes that the other comments received on the definition of "study director" addressed the concept rather than the definition, and these comments are dealt with under the discussion of § 58.33 (see paragraphs 59 through 74, below).

APPLICABILITY TO STUDIES PERFORMED UNDER GRANTS AND CONTRACTS

37. Two comments requested revision of § 58.10 to specify clearly that the sponsor is ultimately responsible for data validity, even if the data are obtained by a sponsor from a grantee or contractor.

The Commissioner concludes that no revision of § 58.10 is necessary. All persons involved in a nonclinical laboratory study are responsible for part or all of the study, depending upon the extent of their participation. Although a sponsor who submits studies to FDA bears the responsibility for the work performed by a subcontractor or grantee, that fact in no way relieves a grantee or subcontractor from individual responsibility for the portion of the study performed for the sponsor. Indeed, the purpose of the requirement that the sponsor notify a grantee or subcontractor that the work being performed is a part of a nonclinical laboratory study which must be conducted in compliance with the good laboratory practice regulations is to assure that all parties submitting data are aware of their responsibilities under the regulation.

38. Several comments requested exemption for certain specialized services which are not commonly available, e.g., ototoxicity studies with diuretics. The comments stated that these specialized services would probably not be available to them if the stringent requirements of the regulations had to be met by the service organization.

The Commissioner concludes that certain specialized services cannot be exempted from these regulations. The specialized services may contribute in large measure to the agency decision to approve a research or marketing permit. If the studies are intended to provide safety data in support of an application for a research or marketing permit, their conduct falls within the scope of these regulations.

INSPECTION OF A TESTING FACILITY

39. Comments on the inspection provisions (§ 58.15) expressed concern regarding the competence and scientific qualifications of FDA investigators.

The agency has endeavored, through a specialized training program, to assure that FDA investigators are competent to perform good laboratory practice inspections. The EILP program is new, and training and evaluation will continue to improve it. The results of the pilot inspection program and the manner in which it was conducted should provide added assurance to testing facility management regarding the competence of FDA investigators. The quality of the program is not, however, dependent on the competence or training of any single individual. Inspection of findings are always subject to supervisory review within the agency, and no official action may be taken without concurrence of a number of qualified persons.

40. Several comments stated that agency inspection should be limited to

those facilities under current FDA legal authority.

The scope of the regulations and the definition of a "nonclinical laboratory study" define those studies covered by the regulations. The agency intends to inspect all facilities which are conducting such studies. Many of these facilities are subject to inspection under express statutory authority vested in FDA. As noted in the preamble to the proposal (41 FR 51220):

Inspections of many, perhaps most, testing facilities will not be conditioned upon consent. Under section 704(a) of the act, FDA may inspect establishments including consulting laboratories, in which certain drugs and devices are processed or held, and may examine research data that would be subject to reporting and inspection pursuant to section 505 (l) or (j) or 507 (d) or (g) of the act. In addition, any establishment registered under section 510(h) of the Act is subject to inspection under section 704 of the act. Thus, most manufacturing firms that conduct in-house non-clinical laboratory studies on drugs and devices, and those contract laboratories working for such firms, would be subject to FDA inspection whether or not they consented.

Facilities that are not subject to statutory inspection provisions will be asked to consent to FDA inspection. The absence of any statutory authorization does not bar FDA from asking permission to conduct an inspection, and the agency should not bar itself from seeking permission. Thus, the proposal in the comment is not accepted.

41. Several comments requested that FDA make its enforcement strategy known as promised in the preamble to the proposal.

The enforcement strategy was discussed in the preamble to the proposal (41 FR 51216) and is amplified in the compliance program which implements this regulation. The compliance program is publicly available and may be obtained by sending a written request to the agency official whose name and address appear at the beginning of this preamble as the contact for further information.

42. Two comments on § 58.15 as proposed requested that the requirement that the testing facility permit inspection by the sponsor be deleted. The comments argued that the rights and obligations of a sponsor and its laboratory are a matter of contract between them alone, and not a proper subject for government regulation.

The Commissioner has considered this issue, is persuaded that the comments are correct, and has deleted the phrase "the sponsor of a nonclinical laboratory study." At the same time, however, the Commissioner reemphasizes that, because a sponsor is responsible for the data he or she submits to the agency, the sponsor may well wish to assure that the right to inspect a

testing facility is included in any contract.

43. Other comments suggested that the sponsor should accompany the FDA investigator during an inspection of a contract testing facility and that FDA access to data should require the sponsor's consent.

The Commissioner disagrees with these comments. An agency investigator may be inspecting the results of studies from several sponsors during an inspection. The logistics required to notify and arrange for several sponsors to accompany an investigator, or to obtain sponsor consent to information release, would be unworkable. FDA's practice of unannounced inspections has proved to be an effective and efficient use of scarce resources. Because of resource limitations, FDA cannot inspect each facility as often as it would like to, and the Commissioner finds that the possibility of unannounced FDA inspections at any time motivates compliance.

44. Many comments were concerned that trade secret information obtained during the inspection would be released by FDA.

The Commissioner notes that trade secrets obtained as a result of an inspection are fully protected under the provisions of section 301(j) of the act (21 U.S.C. 331(j)), as well as 18 U.S.C. 1905 and the Freedom of Information Act (5 U.S.C. 552(b)(4)) and the FDA's implementing regulations (21 CFR 20.61). Interested parties may refer to the agency's public information regulations (21 CFR Part 20), which govern agency release of documents.

45. One comment requested that the results of government laboratory inspections be made public.

The Commissioner notes that no distinctions will be made between government or nongovernment laboratories. The results of an inspection of testing facilities will be available after all required followup regulatory action has been completed.

46. The phrase "and specimens" has been added to § 58.15(a). The Commissioner finds that examination of specimens may be required to enable the agency, where necessary, to reconstruct a study from the study records.

47. Many comments stated that the inspection of records should not extend to certain records compiled by the quality assurance unit.

The Commissioner agrees and has exempted from routine inspection those records of the quality assurance unit which state findings, note problems, make recommendations, or evaluate actions taken following recommendations. These exemptions from inspection are discussed in greater detail under the discussion of § 58.35.

48. A new paragraph (b) has been added to § 58.15. This paragraph is similar to proposed § 58.200 and reiterates that a determination that a non-clinical laboratory study will not be considered in support of an application for a research or marketing permit does not relieve an applicant from any obligation under any applicable statute or regulation (e.g., 21 CFR Parts 312, 314, 514, etc.) to submit the results to FDA. If a testing facility refuses inspection of a study, FDA will refuse to consider the study in support of an application for a research or marketing permit. This refusal, however, does not relieve the sponsor from any other applicable regulatory requirement that the study be submitted.

ORGANIZATION AND PERSONNEL

PERSONNEL

49. A number of comments addressed the definition of training, education, and experience in § 58.29. Several comments considered such references too vague; several others suggested that appropriate qualifications be established by professional peer groups.

It would be inappropriate, if not impossible, for FDA to specify exactly what scientific disciplines, education, training, or expertise best suit a specific nonclinical laboratory study. These factors, which vary from study to study, are left to the discretion of responsible management and study directors. They are responsible for personnel selection and for the quality and integrity of the data these personnel will collect, analyze, document, and report. The Commissioner urges, however, that management and study directors carefully consider personnel qualifications as they relate to a particular study. The agency has uncovered instances, discussed in the preamble of the proposal (41 FR 51207), in which the conduct of a study by inadequately trained personnel resulted in invalid data. Although the Commissioner recognizes the value of certification by professional peer groups, he does not agree that the concept is appropriate for regulatory purposes.

50. Several comments said the study director should be given responsibility for assurance of qualifications of personnel.

The Commissioner agrees that, generally, the study director will be responsible for ensuring that personnel selected to conduct a nonclinical laboratory study meet necessary educational, training, and experience requirements. The Commissioner notes, however, that management also has selection and hiring responsibilities and privileges.

51. One comment stated that the requirement of § 58.29 that each individ-

ual engaged in the conduct of a study have sufficient training or experience to enable the individual to perform the assigned function should be limited to those personnel engaged in supervision and collection and analysis of data.

The Commissioner disagrees. These factors are important and should be considered for personnel other than supervisors or those engaged in collection and analysis of data. The approach suggested by the comment would ignore the fact that specific expertise is required, for example, by animal caretakers, physical science technicians, and by persons using pesticides near animal-holding areas. While the degree of education, training, and experience necessary for these positions will be quite different from the qualifications necessary for supervisors or scientific staff, the need for sufficient training or experience is no less important.

52. One comment pointed out the appropriateness of changing the term "person" to "individual" in § 58.29(a).

Because the term "person" as defined in § 58.3(h) includes partnerships, corporations, etc., the Commissioner agrees that "individual" is the proper term and has so amended § 58.29(a).

53. Seventeen comments questioned the use of, or objected to reference to, the term "curriculum vitae" for non-technical personnel such as animal caretakers, as required in proposed § 58.29(b).

Another comment asserted that the requirement infringed on management's prerogatives without specifying how any such infringement occurred. One comment stated that the requirement that such records be retained after termination of employment was unnecessarily cumbersome.

The Commissioner does not agree that the requirement infringes on management's prerogatives. However, the Commissioner agrees with the remaining comments and has revised the section. "Curriculum vitae" has been changed to "summaries of training and experience plus job descriptions." Reference to the maintenance of records of terminated employees is deleted from this section because the requirement is redundant to the record retention requirements set forth in § 58.195(e).

54. Ten comments said the wording of § 58.29(c), relating to "sufficient numbers of personnel" and to "timely" conduct of the study, was vague.

The Commissioner purposely left the paragraph broad in context and coverage because differences in types of studies preclude any specific approach to defining numbers of personnel. The precise number of personnel

required for a specific study, as well as for all ongoing studies, is a management decision. FDA experience, however, indicates that a shortage of qualified personnel can lead to inadequate or incomplete monitoring of a study and to delayed preparation and analysis of results, and the numbers of personnel conducting a study should be sufficient to avoid these problems.

55. Ten comments requested deletion of § 58.29(d) or clarification of the language regarding employee health habits, stating that the section was too vague and that an employer was responsible for health habits only at work. One comment submitted alternate language.

The Commissioner adopts with modifications the alternate language. The paragraph now requires only that personnel take necessary personal sanitation and health precautions to avoid contamination of test and control articles and test systems.

56. Several comments asked that the term "laboratory" in § 58.29(e), as applied to protective clothing, be deleted because it is too restrictive. Other comments suggested that the requirement that clothing be changed as often as necessary to prevent contamination be eased by changing "prevent" to "help prevent." Four related comments requested modification to reflect only "contamination affecting validity of studies."

The Commissioner agrees to the elimination of "laboratory" as applied to clothing. The provision of specialized clothing is, however, an established and well-known procedure for preventing contamination in a variety of situations. The Commissioner disagrees with any suggested modification of this section which weakens the intent of the regulation. The objective is to prevent contamination of the test system.

57. A number of comments addressed several aspects of § 58.29(f) regarding personal illnesses, personal health records, types of illnesses, and records of illnesses. Comments said disclosure of medical records was an invasion of privacy and of little relevance to the proper conduct of a non-clinical laboratory study.

The Commissioner agrees that documentation of personal illnesses may constitute an unwarranted invasion of privacy, and this requirement is deleted. The Commissioner disagrees with the requests for deletion of the entire paragraph, noting the relationship between personnel health and possible contamination of test systems. Revised § 58.29(f) requires individuals with illnesses that may adversely affect the quality and integrity of nonclinical laboratory studies to be excluded from direct contact with test and control articles and test systems.

All personnel should be instructed to report such medical conditions to their immediate supervisor, who should protect test systems from personnel reporting as ill.

TESTING FACILITY MANAGEMENT

58. Many comments on the responsibilities of the study director objected that some of the responsibilities assigned to the study director were more properly assigned to management.

The Commissioner agrees that several of the responsibilities previously assigned to the study director should be assigned to the testing facility management. For clarification, a new § 58.31 is added to the regulations. It is management's responsibility to assure that for each study there is a study director and an independent quality assurance unit, as required by the regulations. It is also management's responsibility to ensure that any deviations from the regulations which are reported by the quality assurance unit are, in turn, reported to the study director and that corrective actions are both taken and documented. Designating management responsibilities in this manner merely clarifies the fact that the study director should be viewed as the chief scientist in charge of a study. Duties which are more administrative than scientific are the responsibility of management; however, management may delegate appropriate administrative duties to the study director.

STUDY DIRECTOR

59. More than 50 comments addressed the scope of responsibilities proposed for the study director. Many comments stated that these responsibilities were much too broad for one person.

In the proposal, the Commissioner advanced the concept of a single fixed point of responsibility for overall conduct of each nonclinical laboratory study. Experience has demonstrated that if responsibility for proper study conduct is not assigned to one person, there is a potential for the issuance of conflicting instructions and improper protocol implementation. The study director is charged with the technical direction of a study, including interpretation, analysis, documentation, and reporting of results. As discussed in paragraph 58, several of the responsibilities proposed for the study director have been transferred to testing facility management. This transfer should allay concerns regarding the magnitude of the responsibilities assigned to the study director.

60. Nine comments object to the term "ultimate" as applied to the study director's responsibility.

The Commissioner agrees that "ultimate" responsibility for the study

rests with facility management and/or the sponsor. Therefore, the word "ultimate" has been replaced by "overall" in § 58.33.

61. Several comments argued that more than one study director should be allowed for each study.

The Commissioner rejects these comments. As noted above, there must be a single point of responsibility for overall technical conduct of the study. The potential for conflicting instructions and confusion in study implementation is too great to diffuse the responsibility by, for example, study direction by a committee. The regulation does not, however, preclude the study director from directing more than one study.

62. Many comments stated that the requirements would interfere with management's prerogatives to organize and conduct studies as it so chooses.

The requirement that the study director be the single point of responsibility for technical conduct of the study need not interfere with normal delegation of authority by management.

63. Five comments argued that the proposed requirements for study director and quality assurance unit were duplicative.

The Commissioner has carefully reviewed the proposal and comments and has clearly separated the responsibilities in the final regulation to avoid duplication. The first sentence in § 58.33 has been revised to specify clearly that each study shall have a study director. The second sentence has been revised to amplify the concept: "The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results and represents the single point of study control."

64. One comment suggested revising § 58.33(a) to specify that the sponsor must approve the protocol and the study director must approve any change.

The Commissioner advises that § 58.120(a)(15) requires that the sponsor approve the protocol, and § 58.120(c) requires that the study director approve any changes or revisions to the protocol. The language in § 58.33(a) has been revised to reference § 58.120.

65. Five comments objected to the proposed requirement that the study director assure that test and control articles or mixtures be appropriately tested. The comments argued that this was not a proper function of the study director.

The Commissioner agrees that this responsibility is more properly assigned to testing facility management.

Therefore, the requirement has been transferred to § 58.31(d).

66. Three comments suggested that, rather than the study director assuring that test systems are appropriate, the study director should assure that the test systems are as specified by the protocol.

The Commissioner agrees that the determination of the appropriateness of the test system is a scientific decision beyond the scope of these regulations. Section 58.33(d) has been revised to state: "Test systems are as specified in the protocol."

67. Four comments argued that the scheduling of personnel, resources, facilities, and methodologies was not a proper requirement for the study director.

The Commissioner agrees that this scheduling is beyond the scope of the study director's responsibilities and has, therefore, transferred it to the responsibilities of testing facility management in § 58.31(e).

68. Two comments object to the requirement that personnel clearly understand the functions they are to perform.

The Commissioner finds that it is essential that personnel be adequately trained to assure the integrity and validity of the data. However, the Commissioner concludes that training is a proper responsibility of testing facility management and has transferred the requirement to § 58.31(f).

69. Three comments suggested deletion of the phrase "and verified" from the proposed requirement that the study director assure that all data are accurately recorded and verified. Four comments requested definition of the term "verified."

The Commissioner disagrees with the requested deletion. Recording and verifying data are key operations in the successful completion of a study. The Commissioner intends that the study director assure that data are technically correct and accurately recorded. "Verified" is used in its ordinary sense of "confirmed" or "substantiated." The process by which verification is achieved may be determined by the study director.

70. One comment stated that proposed § 3e.31(a)(8) merely repeated proposed § 3e.31(a)(7).

The Commissioner finds that the two sections can be combined for clarity. Accordingly, § 58.33(c) now reads "unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented."

71. One comment stated that the requirement that the study director assure that responses of the test system are documented is unreasonable.

The Commissioner disagrees. Assuring that all experimental data including unforeseen responses to the test system are accurately observed and documented is a critical part of study conduct and is a responsibility properly assigned to the study director.

72. Two comments stated that the requirement that the study director assure that good laboratory practice regulations are followed either should be modified to make it more flexible or should be deleted. One comment suggested that the study director should be allowed to delegate the responsibility.

The Commissioner rejects these comments. The regulations constitute an effective means to aid study directors in achieving better control of complex studies. Responsibility for assuring compliance properly rests with the study director. While delegation of authority is always the prerogative of a manager, responsibility cannot be delegated.

73. Several comments stated that the requirement that the study director assure that study documentation is transferred to the archives is redundant to § 58.190.

The Commissioner does not agree that the sections are redundant. Section 58.190 requires that the study records be retained, and § 58.33(f) requires that the study director assure that the records are transferred for retention. The phrase "and other information to be retained" has been deleted from § 58.33(f) because the phrase is subsumed by raw data, documentation, protocols, specimens and final reports.

74. Thirteen comments questioned the proposed approach to study director replacement, specifically objecting to the requirement that justification of such replacement be documented and retained as raw data. The comments argued that justification carries a negative connotation and that replacement of a study director is a management prerogative.

The Commissioner is persuaded that replacement of the study director should remain within the discretion of management and that the requirement that justification for such replacement be documented and retained is an inappropriate subject for these regulations. Consequently, the requirement for justification for such replacement has been deleted. The requirement that the study director be replaced promptly when necessary has been transferred to § 58.31(b).

QUALITY ASSURANCE UNIT

75. More than 100 comments objected to part or all of § 58.35 as proposed. Many comments questioned the need for a quality assurance unit as proposed. Some comments stated that the

establishment of such a unit would increase the administrative burden and costs of performing nonclinical studies to the point of forcing small facilities out of business. Others stated that the provisions would interfere with management's prerogatives to organize the facility or with the informed scientific judgment of principal investigators or study directors.

The Commissioner has retained the requirement that each testing facility have a quality assurance unit (QAU) to monitor the conduct and reporting of nonclinical laboratory studies. In view of the potential gain to management, to sponsors, and to FDA, through the added assurance of well-conducted studies, increased costs, if any, are justified. The quality assurance unit need not be a separate organizational entity composed of personnel permanently assigned to that unit. All nonclinical studies falling within the scope of this regulation must be monitored by a quality assurance unit composed of at least one person. Within this framework, management retains its organizational prerogatives. Because different individuals may be responsible for quality assurance functions at different times, it is important that quality assurance unit records be centrally located, and § 58.35(e) has been modified to so require. The regulations permit a study director for a particular study to serve as a part of the quality assurance unit or as the quality assurance unit for a different study. However, for any given study a separation must exist between individuals actually engaged in the conduct of a study and those who inspect and monitor its progress. In those situations in which several different individuals are performing the quality assurance functions for different studies, each such individual must maintain that portion of the master schedule sheet which relates to the study he or she is monitoring. This means that several people may be responsible for maintaining the master schedule sheet. Because the function of the quality assurance unit is administrative rather than scientific, the Commissioner does not agree that the functions of a QAU will interfere with the study director's control of the overall technical conduct of the study. In order to emphasize this point, the following language has been added to § 58.35(a): "For any given study the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study."

76. Sixteen comments objected to the word "unit" in the term "quality assurance unit" and suggested alternate words such as "function" or "program."

The Commissioner has elected to preserve the word "unit" to conform to similar wording in other regulations such as the current good manufacturing practice regulations. The Commissioner agrees, however, with the rationale of the comments that the important objective of this section is that there be a quality assurance function operating for each nonclinical study. As indicated in paragraph 75, the exact organizational means by which this function is achieved is the prerogative of facility management and may vary from facility to facility.

77. Numerous comments addressed the composition of the quality assurance unit. Four comments sought inclusion of criteria for education, training, and experience of QAU personnel. Seven comments indicated that compliance with this section was impractical because of a shortage of people qualified to staff such a unit.

The Commissioner has not attempted to specify the qualifications of quality assurance personnel because qualifications should be determined by management and will vary according to the type of facility and the types of studies conducted by each facility. Because the function of the quality assurance unit is to assure compliance with procedural and administrative requirements rather than to oversee the technical aspects of study conduct, QAU personnel need not be limited to professional personnel and/or scientists. The Commissioner does not agree, therefore, that there exists a serious shortage of qualified people to fulfill this function.

78. Two comments indicated that the quality assurance unit should be composed of outside consultants in order to assure the independence of the function. One comment requested that quality assurance unit membership be restricted to employees of the facility.

The Commissioner notes that the quality assurance functions may be performed by outside consultants. This fact should enable small facilities or facilities conducting nonclinical laboratory studies for submission to the FDA on an irregular basis to meet the quality assurance requirements in a cost-effective manner. At the same time, the Commissioner does not agree that the QAU function must be performed by an outside body. The organizational separation of the QAU from the study team should be sufficient to assure objective monitoring by the QAU.

79. Four comments questioned the last sentence in § 58.35(a) as proposed, stating that it seemed to require monitoring of some studies by two QAUs—that of the sponsor and that of the contract facility.

The Commissioner has deleted from § 58.35(a) the sentence in question. The QAU of the testing facility is solely responsible for fulfilling the quality assurance functions for studies conducted within that facility. In those cases where portions of a study, e.g., feed analysis, are performed by a contract facility which, because it is not itself a nonclinical facility, does not have a QAU, the person letting the contract, and not the contract facility, is responsible for the performance of the quality assurance functions.

The Commissioner believes that the mechanism by which a sponsor is assured of the quality of nonclinical studies performed for it under contract is a matter that can be left to the contracting parties and need not be addressed in these regulations.

80. Three comments suggested that testing facilities be licensed or certified in lieu of having an ongoing quality assurance unit.

The Commissioner considered such an approach and rejected it before publishing the proposed regulations. (See 41 FR 51208-51209.) No persuasive arguments for changing this decision were presented in the comments. The diversity in the size and nature of nonclinical testing facilities subject to the provisions of these regulations makes licensing or certification procedures impractical. The regulation is intended to assure the quality and validity of the data obtained by each nonclinical laboratory study, and the QAU provides a mechanism to monitor each ongoing study. Licensing a testing facility could not achieve the same result.

81. Many comments objected to the provisions of § 58.35(b)(1) which require that the quality assurance unit maintain a master schedule sheet of all nonclinical laboratory studies. Some comments believed the requirement was excessive, while others questioned the proposed format and contents of the list. One comment pointed out that not every study includes all items listed.

The Commissioner is convinced that maintenance of a master schedule sheet is essential to the proper function of the Quality Assurance Unit. Only through such a mechanism can management be assured that the facilities are adequate and that there are sufficient numbers of qualified personnel available to accomplish the protocols of all nonclinical studies being conducted at a facility at any given time.

Upon careful review of the items required to be listed, the Commissioner agrees that the requirement that animal species be identified may be deleted because the requirement that "test system" be listed adequately

covers this point. He has, in addition, deleted the examples of study types because he agrees that including the information is not necessary to achieve objectives of this section. The Commissioner has further reworded this section to eliminate reference to whether the final report has been approved for submission to the sponsor because the language was strictly applicable only to studies done under contract. The revised language simply requires that the status of the final report be listed.

82. Nine comments objected that § 58.35(b)(2) required too much duplicative paper.

The Commissioner has concluded that the QAU must maintain copies of study protocols to assure that they are followed and amended in accordance with the further provisions of these regulations. The Commissioner agrees that the requirement that the QAU maintain copies of all standard operating procedures would substantially increase the volume of records needed to be retained by this unit. Because there should be many copies of standard operating procedures present throughout the facility which should be freely available to QAU members, the Commissioner has deleted the requirement that these be maintained by the QAU.

83. Fifteen comments suggested that § 58.35(b)(3) be deleted on the basis that FDA should not dictate how the QAU achieves its objectives. One comment suggested that "inspect" be changed to "audit."

The Commissioner remains convinced of the need for a formal mechanism through which the QAU maintains oversight of the conduct of a study. Such a mechanism must be based on direct observation in order that the independence of the QAU be preserved. The Commissioner has retained the word "inspect" in preference to "audit." "Inspect" more accurately conveys the intent that the QAU actually examine and observe the facilities and operations for a given study while the study is in progress, whereas "audit" could be interpreted to mean simply a detailed review of the records of a study. Because the QAU function is to observe and report the state of compliance with the regulations and to determine whether the protocol is being followed rather than to verify the results of a study, "inspect" more properly conveys the agency's intent.

84. Fourteen comments addressed the need to inspect "each phase of a study * * * periodically," seeking clarification or different language. Nine of these comments called for the use of random sampling procedures in choosing studies or phases of studies to inspect in order to decrease the work-

load and resource requirements of the QAU.

The Commissioner does not agree that random sampling would be an adequate method of evaluation in the nonclinical laboratory setting. In situations which involve the repetition of similar or identical procedures, random sampling can provide an adequate means of quality control. Here, however, the differences among study operations and among the personnel conducting them invalidate any assumption that the conduct of one phase of one study is representative of the conduct of that phase of another or of other phases of a single study. The term "each phase" is intended to emphasize the need for repeated surveillance at different times during the conduct of a study so that each critical operation is observed at least once in the course of the study. The term "periodically" is retained to indicate the need for more than one inspection of certain repetitive continuing operations that are part of the conduct of longer term studies such as animal observations and diet preparation.

85. Many comments objected to the proposed requirement that any problems found by the QAU be brought to the attention of management and appropriate responsible scientists. Some felt that this would require that excessive resources be spent on minor problems. Others felt that notification of appropriate supervisory personnel rather than management was sufficient.

The Commissioner agrees that only those problems likely to affect the outcome of the study need to be brought to the immediate attention of personnel who are in a position to resolve those problems, and the language of § 58.35(b)(3) has been changed accordingly. The term "management" in its ordinary usage means appropriate supervisory personnel and has not, therefore, been changed.

86. More than 40 responses to proposed § 3e.33(b)(4) objected to the specific time frames required for evaluation. Several comments suggested that the paragraph be deleted. Others objected to the specific requirements, and still others stated that appropriate times for evaluations should be selected by management.

The Commissioner advises that periodic inspection is necessary and that the time periods specified are the minimum required to assure that a study is being conducted in compliance with the regulation. Should deviations be found during the periodic inspections, there may still be time to take corrective action. The Commissioner has, however, determined that inspection of studies lasting less than 6 months need only be conducted at intervals adequate to assure the integri-

ty of the study and that specific time intervals for such studies need not be set out in this regulation. The requirement that studies lasting more than 6 months be inspected every 3 months remains unchanged. The section has been added to § 58.35(b)(3).

87. Several comments requested that the phrase "complete evaluation" in proposed § 3e.33(b)(4) be clarified.

The Commissioner has changed the term "complete evaluation" to "inspect." The function of the QAU is to inspect studies at specified intervals to maintain records required by this regulation, and to report to management and the study director deviations from the protocol and from acceptable laboratory practice. Evaluation of any reported deviations is left to the study director and to management.

88. Fifteen comments sought deletion of § 58.35(b)(4), which requires the periodic submission of status reports to management and the study director. Three comments questioned the need to note problems and corrective action taken.

The Commissioner has retained this provision as proposed. Only through the submission of such status reports can management be assured of the continuing conformity of study conduct to the provisions of these regulations. Because § 58.35(b)(3) has been revised to require that only significant problems be reported immediately to management, the periodic status report becomes even more important as a means of informing management of minor problems and normal study progress. The status reports are needed to document problems and corrective actions taken so that management can be certain that quality is being maintained and that management intervention is not required. The timing of such reports may be determined by management.

89. Six comments objected that the term "prior" preceding "authorization" in § 58.35(b)(5) was too restrictive. The comments pointed out that unforeseen circumstances may prevent prior authorization for deviations from standard procedure and that the QAU should be concerned with the documentation of the deviation, not with whether prior authorization existed. Two comments stated that the QAU cannot assure that deviations do not occur but can determine, by inspection, whether deviations were documented.

The Commissioner is persuaded that prior authorization cannot always be obtained. For example, a fire in the facility would necessitate immediate action. The Commissioner agrees that documentation of the deviation rather than prior authorization is the important point and has deleted "prior" and added "documentation." In addition,

"assure" has been changed to "determine" to respond to the comments and to reflect more accurately the Commissioner's intent. Section 58.35(b)(5) now reads: "Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation."

90. Several comments objected to the wording of § 58.35(b)(6), which states that the QAU shall review the final study report. The comments stated that such review requires a scientific judgment and is not an appropriate function for the QAU to perform. One comment suggested that the requirement should be modified to allow for random sampling rather than a complete review of all studies.

The Commissioner agrees that the QAU should not attempt to evaluate the scientific merits of the final report. Therefore, he has modified the paragraph. The QAU must however ensure that the final report was derived from data obtained in accordance with the protocol. Data in the final report significantly contributing to the quality and integrity of a non-clinical laboratory study shall be reviewed. A random sampling approach is not acceptable.

90a. The Commissioner has added to § 58.35 new paragraph (b)(7) which requires that the QAU prepare and sign a statement to be included with the final report which specifies that dates inspections of the study were made and findings reported to management and the study director. This requirement clarifies the fact that QAU review should extend through the completion of the final report and provides a mechanism for documenting that the review has been completed. A conforming section has been added to the final report requirements of § 58.185 as new paragraph (a)(14).

91. Many comments argued that requiring all portions of a quality assurance inspection to be available for FDA inspection might serve to negate their value as an effective management tool for ensuring the quality of the studies during the time in which the studies are being conducted.

The Commissioner shares the concerns of the comments that general FDA access to QAU inspection reports would tend to weaken the inspection system. He believes that FDA's review of quality assurance programs is important, and he recognizes the need to maintain a degree of confidentiality if QAU inspections are to be complete and candid. Therefore, the Commissioner has decided that, as a matter of administrative policy, FDA will not request inspections and copying of either records of findings and problems or records of corrective actions recommended and taken; and §§ 58.15

and 58.35(c) have been revised to separate those records subject to regular inspection by FDA from those records not subject to such inspection. Exempt from routine FDA inspection are records of findings and problems as well as records of corrective actions recommended and taken. All other records are available. Although the Commissioner is deleting the requirement in new § 58.35(d) that testing facility management shall, upon request by an authorized employee, certify in writing that the inspections are being performed and that recommended action is being or has been taken. Upon receiving such a request, management is required to submit the certification of compliance. A person who submits a false certification is liable to prosecution under 18 U.S.C. 1001.

The one exception to FDA's policy of not seeking access to records of findings and problems or of corrective actions recommended and taken is that FDA may seek production of these reports in litigation under applicable procedural rules, as for otherwise confidential documents.

92. Many comments objected that requiring internal quality assurance audits to be available to the agency might violate the constitutional privilege against compelled self-incrimination.

The Commissioner disagrees with the comments. It is settled that the privilege against compelled self-incrimination is an individual privilege relating to personal matters; the privilege is not available to a collective entity, such as a business enterprise, or to an individual acting in a representative capacity on behalf of a collective entity. *California Bankers Ass'n v. Schultz*, 416 U.S. 21, 55 (1974); *Bellis v. United States*, 417 U.S. 85 (1974); *United States v. Kordel*, 397 U.S. 1, 8 (1970); *Curcio v. United States*, 354 U.S. 118, 122 (1957); *United States v. White*, 322 U.S. 694, 699 (1944); *Wilson v. United States*, 221 U.S. 361, 382-384 (1911); *Hale v. Henkel*, 201 U.S. 43, 74-75 (1906). Even for individuals, the privilege against compelled self-incrimination is inapplicable where a reporting requirement is applied to an "essentially noncriminal and regulatory area of inquiry," where self-reporting is the only feasible means of securing the required information, and where the requirement is not applied to a "highly selective group inherently suspect of criminal activities" in an "area permeated with criminal statutes." *California v. Byers*, 402 U.S. 424, 430 (1971); *Marchetti v. United States*, 390 U.S. 39 (1968); *Albertson v. SACB*, 382 U.S. 70, 79 (1965); *Shapiro v. United States*, 335 U.S. 1 (1948).

ACCESS TO PROFESSIONAL ASSISTANCE

93. Comments on proposed § 3e.35 suggested rephrasing the statement to specify that professional assistance be authorized by the study director, that it be either in person or by telephone, that it be available within a reasonable period, and that reference to availability of a veterinary clinical pathologist be included. Other comments suggested that the concept was duplicative of the function of the study director and should be deleted.

The Commissioner proposed this requirement to assure that a scientist or other professional would be available to respond to requests for assistance or consultation from less experienced personnel. However, because management is responsible for assuring that personnel are available and that personnel clearly understand the functions they are to perform, and because the study director has overall responsibility for the technical conduct of the study, access to professional assistance is a matter best left to management's discretion. Therefore, the section is deleted from the final regulations.

FACILITIES

GENERAL

94. Many comments requested definition or clarification of the terms denoting separation (i.e., separate area, defined area, separate space, and specialized area), which are used in §§ 58.41, 58.43, 58.47, 58.49, and 58.90.

The Commissioner's intent in proposing that there be defined (and, where required, separate or specialized) areas in a testing facility was to assure the adequacy of the facility for conducting nonclinical laboratory studies. This intent is more clearly stated in the revised second sentence of § 58.41, which now reads: "It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study." The important point is that the facility be designed so that the quality and integrity of the study data is assured. The manner in which the separation is accomplished may be determined by testing facility management.

Adequate separation may be, in various situations, a function of such factors as intended use of the specific part of the facility, space, time, and controlled air. The broad variety of test systems, test and control articles, and the size and complexity of testing facilities preclude the establishment of specific criteria for each situation. For these reasons the Commissioner declines to include in the regulation either a definition or specific examples of methods for achieving adequate separation.

95. One comment suggested that a number of additional animal care and facility requirements be added to the regulations. The suggestions included, e.g., ambience to assure nonstressful conditions; ventilation and room access arranged to prevent cross contamination; and surveillance of animal health before and during a test or experiment.

The Commissioner concludes that no additional requirements need to be added because the regulation, as it stands, adequately covers the additions proposed by the comments. For example, ventilation and room access arranged to prevent cross contamination are addressed by the degree of separation requirement in § 58.41.

ANIMAL CARE FACILITIES

96. Many comments suggested that accreditation of animal care facilities by a recognized organization should provide adequate evidence that a testing facility is in compliance with § 58.43(a). One comment suggested accreditation by recognized organizations for analytical laboratories.

Although the Commissioner is aware of the value of accreditation programs, he cannot delegate FDA's responsibility for determining compliance with these regulations to an organization over which FDA has no authority. Few, if any, accreditation programs cover the same areas covered by this regulation. Furthermore, the Commissioner is unaware of any facility accreditation program which is mandatory. The agency's obligation to inspect a testing facility for overall compliance would not be altered by the fact that a facility was otherwise accredited.

97. Numerous comments objected to the requirements concerning separation of species, isolation of projects, and quarantine of animals as impractical and not necessary in all instances, e.g., separation of species in large animal studies and quarantine of all newly acquired animals. Some of the comments stated that the requirements of this section allow no latitude for judgment concerning their applicability.

The Commissioner reiterates that all requirements may not be applicable or necessary in all nonclinical laboratory studies and that the degree to which each requirement should apply in each case can be determined by informed judgment. Because of the variability of nonclinical laboratory studies, a degree of flexibility in applying the requirements of § 58.43(a) is necessary, and the language of § 58.43(a) is amended to read: "A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1) separation of species or test systems, (2) isolation of individ-

ual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals." As noted in the general discussion at the beginning of this preamble, all references to other standards ("The Animal Welfare Act") have been deleted.

98. Several comments suggested that § 58.43(b) be amended to include isolation of test systems with infectious diseases as well as isolating studies conducted with infectious or otherwise harmful test articles.

The Commissioner agrees that test systems with infectious diseases should be isolated. Proposed § 3e.49(b) provided for specialized areas for handling volatile agents and hazardous aerosols. Section 3e.49(b) also provided for special procedures for handling other biohazardous materials. Proposed § 3e.49(c) provided for special facilities or areas for handling radioactive materials.

To clarify all these requirements, the Commissioner has amended § 58.43(b) to read: "A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents." The provisions in proposed § 3e.49(b) and (c) regarding specialized areas for handling volatile agents, hazardous materials and radioactive materials are deleted from § 58.49.

99. One comment on § 58.43(c) suggested that, in addition to the area designated for the care and treatment of diseased animals, a separate area should be provided for animals with contagious diseases.

The Commissioner agrees, and the paragraph is amended to allow for an area for treatment of animals with contagious diseases, and it is to be separate from the area designated for the care and treatment of diseased animals.

100. Several comments questioned the requirement for separate areas for diseased animals, indicating that often such animals are sacrificed rather than treated.

The Commissioner does not agree that a separate area is not always needed for diseased animals. Although diseased animals may be sacrificed, this is not always the case, and it may not always be possible immediately to sacrifice diseased animals. Thus, a separate area should be available for such animals until sacrifice can be accomplished.

101. One comment requested that § 58.43(e), which deals with facility design, construction, and location to minimize disturbances that interfere with the study, should also define the

acoustic and sound-insulating requirements necessary to satisfy this requirement.

The Commissioner concludes that it is impractical to attempt to define acoustic and sound insulation requirements. It would be equally impractical to attempt to define all other types of possible disturbances that might interfere with a study.

ANIMAL SUPPLY FACILITIES

102. One comment asked that § 58.45 be clarified by specifically excluding "carriers" from the storage requirements.

The term "carrier," as used in § 58.113, is the material with which the test article is mixed, e.g., feed. The Commissioner concludes that it is necessary to provide facilities for proper storage of carriers and declines, therefore, to exclude them from the storage requirements.

103. One comment requested deletion of the section, stating that it discusses items not appropriate for FDA concern.

Improper storage of feed, carriers, bedding, supplies, and equipment can adversely affect the results of a study. Therefore, the Commissioner finds these matters to be of legitimate concern to FDA and declines to delete the section.

104. Two comments stated that separate storage space need not be required as long as material is properly stored and does not interfere with the conduct of the study.

The Commissioner agrees with these comments, in principle, but is convinced that storage areas for feed and bedding should be separate from the areas housing the test system to preclude mixups and contamination of the test systems. The section has been modified by adding the words "as needed."

FACILITIES FOR HANDLING TEST AND CONTROL ARTICLES

105. One comment stated that § 58.47, as worded, represented an impossible standard and suggested that use of the "designed to prevent" concept would be more realistic.

The Commissioner rejects this comment. The inherent purpose or "design" of all regulations is to prevent or require some action, and the use of the phrase "designed to prevent" would be an awkward and ambiguous modification of § 58.47.

106. Numerous comments objected to creating the number of separate or defined areas proposed by § 58.47, stating that the volume of testing would make it infeasible to create all the separate areas. One comment asked whether eight separate areas were required.

The Commissioner reiterates that the purpose of this section is to assure that there exists a degree of separation that will prevent any one function or activity from having an adverse effect on the study as a whole. Because of the wide variety of studies covered by these regulations, a degree of flexibility is appropriate in applying these requirements, and the degree to which each requirement should apply in each case may vary. To make this clear, the term "defined" has been deleted from § 58.47. Section 58.47(a) now reads: "As necessary to prevent contamination or mixups, there shall be separate areas for * * *." There is no specific requirement for eight separate areas.

LABORATORY OPERATION AREAS

107. A number of comments stated that § 58.49 required clarification, that in some instances more than one activity could be permitted in the same room, and that certain of the requirements would not be appropriate in every case.

The Commissioner agrees that the section as proposed was subject to misinterpretation. Because of the nature and scope of the types of studies subject to these regulations, it would be inappropriate to set specific uniform requirements for all studies. Therefore, the provisions are revised to make it clear that reasonable judgments regarding area and space requirements may be made on the basis that a particular function or activity will not adversely affect other studies in progress. Proposed § 58.49(b) has been revised, and the references to biohazardous materials has been added to the list of activities in § 58.49(a). (See the discussion at paragraph 98 above.)

108. Two comments suggested that the wording of § 58.49(a) be changed to refer to "adequate" rather than "separate" laboratory facilities, stating that animal studies require that laboratory facilities be available on the immediate premises. One comment requested that provisions be made for the use of outside laboratory facilities.

The Commissioner concludes that the term "separate" is proper in the context of § 58.49(a). He does not agree that laboratory facilities must be available on the immediate premises of the testing facility, and finds that many laboratory functions can be conducted properly in separate buildings or by independent laboratories located outside the testing facility.

109. Two comments on § 58.49(b) stated that the requirement that space and facilities separate from the housing areas for the test systems be provided for cleaning, sterilizing, and maintaining equipment and that sup-

plies should apply only to major equipment.

The Commissioner does not agree. The objective of the requirement is to prevent the occurrence of those adverse effects which might result to a study from the activities of cleaning, sterilizing, and maintaining. No meaningful distinctions based on "major" or "not major" equipment can be made.

110. One comment on § 58.49(b) stated that the proposed wording did not have useful application in all test systems or studies and that the section should be rewritten to focus on the intended principle and not on the way to achieve it.

The section has been revised. It now reads, "separate space shall be provided for cleaning, sterilizing, and maintaining equipment and supplies used during the course of the study." The revised wording grants flexibility in application as long as study results are not affected.

SPECIMEN AND DATA STORAGE FACILITIES

111. Several comments asked whether § 58.51 applied to completed or ongoing studies. Concern was also expressed that limiting access to storage areas to authorized personnel was not feasible.

This section is amended to apply to archive storage of all raw data and specimens from completed studies. The commissioner cannot agree, however, that limiting access of the archives to authorized personnel only is not feasible. Prudence would dictate such limited access even in the absence of a requirement. The potential for misplaced data and specimens is too great to allow unlimited access to the archives.

ADMINISTRATIVE AND PERSONNEL FACILITIES

112. One comment on § 58.53(a) stated that the section was unnecessary because administrative functions had been previously defined in §§ 58.29, 58.33, and 58.35.

The Commissioner notes that this section specifies facilities rather than duties. References to OSHA regulations have been deleted.

EQUIPMENT

EQUIPMENT DESIGN

113. Five comments on § 58.61 stated that the section was fragmented and redundant.

The Commissioner agrees with these comments and has consolidated the section into one paragraph, which reads: "Automatic, mechanical or electronic equipment used in the generation, measurement or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capac-

ity to function according to the protocol and shall be suitably located for operation, inspection, cleaning and maintenance." This consolidation eliminates the fragmentation and redundancy of the proposal and specifies clearly that the requirements are limited to that equipment which, if improperly designed, or inadequately cleaned and/or maintained, could adversely affect study results.

114. Two comments objected to the undefined general terms "adequate" and "appropriate" in § 58.61.

The Commissioner points out that broad terms are necessary because of the wide range of equipment used in the studies covered. Exact design and capacity requirements for each piece of equipment are clearly beyond the scope of these regulations.

115. Four comments on § 58.61 stated that how cleaning is accomplished is irrelevant and that the regulation should emphasize accomplishment rather than ease of accomplishment.

The Commissioner agrees that the primary concern is that adequate cleaning be accomplished. However, past experience has demonstrated that when equipment is not designed and located to facilitate cleaning and maintenance, it is much less likely to be adequately cleaned and maintained.

MAINTENANCE AND CALIBRATION OF EQUIPMENT

116. Five comments suggested that § 58.63(a) should allow the required functions to be performed at the time the equipment is used rather than specifying that the functions be performed regularly.

The Commissioner agrees that performing these functions at the time of use is satisfactory and is amending § 58.63(a) to provide flexibility. The second sentence of this section now reads: "Equipment used for the generation of data shall be adequately tested, calibrated and/or standardized."

117. Two comments suggested that "calibrated" should be changed to "standardized" because the word "calibrated" normally means a performance check against known standards, whereas "standardized" normally means to make uniform.

The Commissioner finds that for some equipment the term "calibrated" is more appropriate and for other equipment the term "standardized" is more appropriate. Revised § 58.63(a) allows application of either term.

118. Two comments suggested that the reference to the use of cleaning and pest control materials is misplaced in § 58.63(a).

The Commissioner agrees that this use is more appropriately addressed under "Testing Facility Operations",

and the requirements have been transferred to § 58.90(i).

119. Comments requested a precise definition of the equipment for which § 58.63(b) requires written standard operating procedures.

The Commissioner advises that because of the range of study and product types covered, such a list is impractical. The language of this section is retained as proposed to encompass the total range of equipment used in conducting nonclinical studies.

120. Eleven comments questioned the appropriateness of designating a responsible individual in § 58.63(b).

The Commissioner has changed "individual" to "person" as defined in § 58.3(h) to allow for designation of an organizational unit.

121. One comment indicated the need for a clear FDA policy regarding primary calibration standards.

The Commissioner concludes that proper standards are the responsibility of management, and these are to be set forth in the standard operating procedures.

122. One comment agreed with the standard operating procedure requirements of § 58.63(b), but suggested a several year phase-in period.

The Commissioner concludes that 180 days is a sufficient time period for developing standard operating procedures. Furthermore, the Commissioner's intent to require such procedures has been known since November 1976, when the proposed regulation was published.

123. Seven comments suggested that the manufacturer's recommendations should be sufficient for standard operating procedures. Additionally, one comment pointed out that maintenance could be subcontracted and a certificate should be allowed.

The Commissioner advises that the regulation does not preclude the use of manufacturer's recommendations as part of the standard operating procedures, nor does it preclude subcontracting maintenance. The Commissioner advises, however, that if a facility decides to subcontract maintenance, that fact does not relieve the facility of the responsibility for maintenance.

124. One comment argued that the requirement that all equipment records specify remedial action to be taken is excessive, and two comments said there are too many variables to specify in advance the remedial action to be taken.

The Commissioner notes that trouble-shooting charts are available for most equipment. The remedial action taken may influence the results of the study and therefore must be documented.

125. Several comments suggested that the equipment for which standard operating procedures are required

be limited by rewording in one of the following ways: "major" equipment, "equipment used in data collection," or "delicate, complex equipment."

The Commissioner has considered the comments and has modified the language of § 58.63(b) to require that standard operating procedures describe in "sufficient" detail the procedures to be used in cleaning, testing, and standardizing equipment. The Commissioner points out that § 58.81(a) (standard operating procedures) states that the written standard operating procedures are to be those which management is satisfied are adequate to ensure the quality and integrity of study data. While the Commissioner does not find it feasible to confine the requirement for standard operating procedures to "major" equipment, he does find that the regulation clearly contemplates that the required procedures need be only as detailed as deemed necessary to assure the integrity of the study data. Simple equipment, therefore, should require only brief standard operating procedures.

126. Five comments suggested that written records for nonroutine repairs should only be required where the nature of the malfunction could affect the validity and integrity of the data.

The Commissioner rejects this suggestion because it is not always possible to make this judgment ahead of time.

127. Many comments argued that the recordkeeping requirements of § 58.63(c) are excessive.

The Commissioner has concluded that the cost of maintaining records of cleaning exceeds the benefits, and this requirement is deleted. However, the requirement for maintaining records of all inspections, maintenance, testing, calibrating and/or standardizing operations is retained because these records may be necessary to reconstruct a study and to assure the validity and integrity of the data.

128. One comment proposed that a new sentence, reading as follows, be added to § 58.63(c): "Where appropriate, the written record noted above may consist of a notation temporarily fastened to the piece of equipment stating when the last specified action with respect to the equipment was taken."

The Commissioner finds that the suggested approach is not precluded by the language of the section as written, but cautions that where such an approach is used, the notations constitute records which must be retained as required by § 58.195(f).

129. One comment asked whether each client of a contract facility must receive a copy of the equipment maintenance and calibration records.

The Commissioner concludes that the regulation does not so require.

TESTING FACILITIES OPERATION

STANDARD OPERATING PROCEDURES

130. Two comments suggested deleting § 58.81 in whole or in part. Several others said the requirements for standard operating procedures were unnecessary and burdensome.

The Commissioner does not agree. The use of standard operating procedures is necessary to ensure that all personnel associated with a nonclinical laboratory study will be familiar with and use the same procedures. These requirements will prevent the introduction of systematic error in the generation, collection, and reporting of data, and they will ensure the quality and integrity of test data that are submitted to FDA to become the basis for decisions made by the agency. The Commissioner recognizes that the requirements for standard operating procedures may place an additional burden on testing facilities, but finds that the resulting benefits should outweigh the burden. The requirements will benefit the public by producing better quality data and will benefit the testing facility by reducing the need to repeat nonclinical laboratory studies because of errors in the data.

131. A few comments suggested that responsibility for the standard operating procedures should be specified.

The Commissioner has concluded that this function should reside with the management of a facility, and the first sentence of § 58.81(a) is revised accordingly.

132. Several comments suggested that the responsibility for authorizing significant changes in established procedures be vested in someone other than management.

The Commissioner disagrees. Because standard operating procedure will often apply to more than one study in a testing facility, the Commissioner believes that significant changes to a standard operating procedure, which could affect several different studies, should be authorized by management.

133. Several comments stated that standard operating procedures should not apply to certain types of test systems, that the requirement would introduce difficulties in open-ended exploratory experimentation and electromedical equipment testing, that the approach would not lend itself to rapidly changing methodology such as mutagenicity testing, and that requiring chemical standard operating procedures for each test and procedure was not realistic.

The Commissioner agrees that routine standard operating procedures should not apply to exploratory stud-

ies involving basic research. He does not agree, however, that electromedical equipment testing should be exempt unless such testing does not fall under the definition of "nonclinical laboratory study." Standard operating procedures are feasible for studies using methods which change rapidly and for studies using any test system. In the case of chemical procedures, the Commissioner finds that it is realistic to require written standard operating procedures for each test.

134. One comment recommended that the phrase "written standard operating procedures" in § 58.81(a) be changed to "documented appropriate operating procedures." The same comment suggested that the term "ensure" in the first sentence of § 58.81(a) be changed to "maintain."

The Commissioner disagrees with both suggestions. The term "standard operating procedures" refers to routine and repetitive laboratory operations. "Appropriate operating procedures," as a phrase, implies that such procedures could be changed at will. The Commissioner also rejects the suggestion that "ensure" be changed to "maintain." The purpose of written standard operating procedures is to ensure the quality and integrity of the data generated in the course of nonclinical laboratory study. The term "maintain" assumes the procedures already in existence are sufficient to ensure the quality and integrity of the data when, in fact, they may not be sufficient.

135. One comment said that the term "adequate" in the first sentence of § 58.81(a) is a nonprecise term.

The Commissioner agrees, but finds that a testing facility may have a broad range of divergent standard operating procedures for many different studies and that it is impractical to define the adequacy of such procedures for all types of tests. A determination of the adequacy of each standard operating procedure is the responsibility of the management of the testing facility.

136. Numerous comments asked what changes or deviations from standard operating procedures should be documented in the raw data, as required in § 58.81(a). One comment said any deviation should be documented, whether authorized or not.

Every deviation or change in a standard operating procedure should be documented in the raw data. The second sentence of § 58.81(a) has been revised for clarity. It now reads: "All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data."

137. Seven comments indicated that it is inappropriate to require that

every minor deviation be documented and reported in writing to the QAU.

The Commissioner agrees that, because the QAU is no longer required to maintain copies of standard operating procedures, it is inappropriate to require that every deviation be reported in writing to the QAU. It is sufficient that all deviations from standard operating procedures be authorized by the study director and documented in the raw data. No exceptions can be made for "minor" deviations. Because any deviation or change may affect the outcome of a study, it is not possible to judge in advance whether or not a deviation is, in fact, "minor."

138. Several comments indicated that the requirement for standard operating procedures should be general in nature.

The Commissioner disagrees. In the proposal, the Commissioner cited evidence from agency investigations of certain testing facilities that had failed to maintain written standard operating procedures of the kind outlined in § 58.81(b). As a result, certain technical personnel were unaware of the proper procedures required, e.g., for care and housing of animals, administration of test and control articles, laboratory tests, necropsy and histopathology, and handling of data. The Commissioner has concluded that a specific delineation of standard operating procedures will allow for uniform performance of testing procedures by personnel and consequent improvement in the quality of the data.

139. Two comments indicated that the requirements for standard operating procedures set out in § 58.81(b) (1) through (12) largely concern animal studies and that this should be so indicated in this section.

The Commissioner agrees that many of the provisions listed in § 58.81(b) are applicable only to studies involving animals. Such is true, however, of many provisions throughout the regulations, and no special mention of the fact is required here. The Commissioner emphasizes that operations requiring standard operating procedures are not limited to those listed in § 58.81(b).

140. One comment suggested that the phrase "and control" be deleted from the first sentence of § 58.81(b)(3), which requires standard operating procedures for test and control articles, because a control article may often be a competitor's product.

The Commissioner does not agree. Where a control article is a commercially available product, its specifications and characterization may be documented by its labeling.

141. Several comments suggested that the last sentence of proposed § 58.81(b)(3), which reads: "The testing program shall be designed to establish the identity, strength, and purity of

the test and control substances, to assess stability characteristics, where possible, and to establish storage conditions and expiration dates, where appropriate" be deleted or suggested that the sentence be transferred to another section.

The Commissioner agrees. The sentence is deleted from § 58.81(b)(3), and appropriate portions of the sentence are transferred to § 58.105(a). The concepts expressed in this sentence properly belong in the section of the regulations relating to "Test and Control Article Characterization." The phrase "testing and administration" has been deleted from the first sentence of § 58.81(b)(3) for the same reason. To specify clearly the Commissioner's intent, "method of" has been added to § 58.81(b)(3) to modify "sampling." Revised § 58.81(b)(3) now reads: "Receipt, identification, storage, handling, mixing and method of sampling of the test and control articles."

142. One comment stated that § 58.81(b)(9), "Histopathology," and § 58.81(b)(8), "Preparation of specimens," were duplicative.

The Commissioner has revised § 58.81(b)(8) to read: "Collection and identification of specimens" to distinguish the requirement from § 58.81(b)(9), "Histopathology." The term "histopathology" covers the examination of specimens, not their collection and identification.

143. Eight comments recommended a rewording of the requirement in proposed § 3e.81(b)(12) that standard operating procedures be established for the preparation and validation of the final study report.

The Commissioner concludes that the requirement should be deleted because the reporting provisions of § 58.185 adequately describe the requirements for final reports. A new paragraph, § 58.81(b)(11), covering "maintenance and calibration of equipment," has been added to reflect the requirements of § 58.63(b).

144. Seven comments suggested that in § 58.81(c) the requirement that standard operating procedures be available at all times to personnel in the immediate bench area be broadened to be within "easy access." Another comment said the location of such materials should be left to the facility's discretion.

The Commissioner has concluded that unless standard operating procedures are immediately available within the laboratory area they are not within "easy access" and may not be consulted by personnel when routine operations are being performed. The first sentence in § 58.81(c) has been edited for clarity, but the requirement remains.

145. Several comments were received regarding § 58.81(c) and the use of

textbooks as standard operating procedures. One comment suggested that textbooks be considered appropriate as part of a standard operating procedure. Two comments assumed that standard operating procedures would permit the incorporation of textbooks by reference. One comment suggested that supplementary material should be written to augment textbooks. An additional comment suggested that textbooks be used in the absence of standard operation procedures.

Standard operating procedures should be set forth in writing, and textbooks may be used as supplements to written standard operating procedures. Reference to applicable procedures in scientific or manufacturer's literature may be used as a supplement to written standard operating procedures. For example, a standard operating procedure could refer to the pertinent pages of any portion(s) of a textbook or other published literature that might be pertinent to a laboratory procedure performed; these supplementary materials need not be incorporated verbatim in the standard operating procedure, but would be required to be immediately available in the laboratory area for the use of personnel. The last sentence of § 58.81(c) is revised to make this point clear. Additionally, § 58.81(d) regarding a historical file of standard operating procedures has been clarified to read: "A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained."

REAGENTS AND SOLUTIONS

146. Numerous comments on § 58.83 said that to require that the labeling of reagents and solutions in laboratory areas include the method of preparation was neither feasible nor necessary.

The Commissioner agrees and is deleting the phrase "method of preparation" from § 58.83 because the method of preparation could be too lengthy to fit readily on the label. The method of preparation of reagents and solutions should, however, be addressed by the standard operating procedures.

147. Several comments stated that the provision for the handling and use of deteriorated materials and materials of substandard quality should specify only that they not be used and should not specify or require their removal from the laboratory because their removal should be left to the discretion of the laboratory.

The Commissioner agrees, and § 58.83 has been revised accordingly.

148. One comment suggested that the phrase "used in nonclinical studies" be substituted for the phrase "in the laboratory areas" in the first sentence of § 58.83.

The Commissioner disagrees with this comment. All reagents and solutions used in a laboratory conducting a nonclinical study should be properly labeled as provided in the regulation to preclude inadvertent mixups of reagents and solutions that are used in such studies with those that are not intended for such use.

149. Two comments suggested that the phrase "Deteriorated materials and materials of substandard quality" in the second sentence of the section be changed to incorporate the terms "reagents" and "solutions."

The Commissioner agrees and is revising the second sentence of § 58.83 accordingly. Revised § 58.83 now reads: "All reagents and solutions in laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used."

ANIMAL CARE

150. Several comments raised the issues of unnecessary animal experimentation and the humane care of animals.

The issue of using animals in laboratory experiments designed to establish the safety of regulated products has been raised many times in the course of agency rulemaking. The position of FDA has been consistent on this issue. The use of animal tests to establish the safety of FDA-regulated products is necessary to minimize the risks from use of such products by humans. The humane care of test animals is a recognized and accepted scientific and ethical responsibility and is encouraged both by various agency guidelines and the Animal Welfare Act. The good laboratory practice regulations should, in fact, encourage the humane treatment of animals used in nonclinical laboratory studies by establishing minimum requirements for the husbandry of animals during the conduct of such studies. In addition, there should occur a reduction in the amount of animal testing that has to be repeated or supplemented because the original studies were inadequate or inappropriate to establish the safety of FDA-regulated products.

151. Numerous comments objected to the incorporation by reference of guidelines and standards proposed in § 58.90(a).

As noted early in the preamble, all references to other standards such as the Animal Welfare Act of 1970 and HEW Publication No. (NIH) 74-23 have been deleted. Section 58.90(a) is revised to read: "There shall be standard operating procedures for the housing, feeding, handling and care of animals."

152. Several comments stated that the quarantine of animals required in

§ 58.90(b) was impossible in some cases, unnecessary under certain conditions, and would prevent the use of certain animals, such as "timed-pregnant" mice. Other comments said the paragraph could be interpreted to require a separate quarantine area or an extensive quarantine time period.

The purpose of this paragraph is to require that the health status of newly received animals be known before they are used. This requires a separate quarantine area where necessary to determine animal health status. The concept of "separate areas" has been previously discussed. In some cases, depending on such factors as the species or type (e.g., time-pregnant) of animal, or the source and the nature of the expected use of the animal, a health evaluation can be made immediately, or soon after arrival, resulting in a very short quarantine period. The regulation does not preclude this type of health evaluation if it is done in accordance with acceptable veterinary medical practice.

153. Several comments stated that quarantine is unnecessary when animals are obtained from reputable or specific pathogen-free sources.

A health evaluation is required of all newly received animals regardless of the supply source, although the source can be a factor in determining the degree or depth of health evaluation required. Seldom can the conditions under which animals are transported from their source be considered certain to preclude the possibility of exposure of the animals to disease.

154. Some comments requested deletion of § 58.90(b) because it duplicates the animal care requirements regulations.

The Commissioner rejects these comments. The agency is responsible for animal care procedures as they pertain to testing facilities conducting nonclinical laboratory studies, and the provisions are appropriately included in § 58.90(b).

155. Several comments said that the requirements of § 58.90(c) and (d) concerning the isolation of known or suspected diseased animals and keeping animals free of disease or conditions that would interfere with the conduct of the study were impractical.

For clarity, these paragraphs are revised and combined in § 58.90(c). This paragraph deals only with those diseases and conditions that might interfere with the study. This excludes a wide range of diseases and conditions and allows the consideration of such factors as etiology and whether the disease is communicable. The section does not require isolation of all animals in a shipment from a study when only one or some of the animals are diseased, and it covers only those ani-

mals that are known or suspected to be diseased.

156. Some comments suggested that specific requirements be provided for the management of diseased animals, and one comment said the veterinary staff should be able to treat diseased animals as they deem proper.

The Commissioner concludes that it is beyond the scope and purpose of these regulations to describe detailed requirements concerning the management of diseased animals and that § 58.90(c) is sufficiently explicit to exclude the use of diseased animals that would interfere with the purpose or conduct of a nonclinical laboratory study. The regulation does not prohibit the treatment of diseased animals if such treatment does not interfere with the study. If treatment will interfere with the study, the diseased animals shall be removed from the study.

157. More than 60 comments objected to or requested revision of proposed § 3e.90(e), which called for the unique identification of all animals used in nonclinical laboratory studies. Fifty-four of the comments addressed specific issues related to this concept, e.g., unique identification of mice, costs of such systems, application to suckling rodents, injury to animals from identification systems, effects of dyes or tattoos, a lack of need in single-dose or short-term experiments, and cage identification instead of animal identification with precautions being taken to prevent animal mixups.

In the absence of a proven and acceptable method of unique identification for small rodents, the Commissioner is revising § 58.90(d) to require appropriate identification for warm-blooded animals, excluding suckling rodents, which require manipulations and observations over extended periods of time. Suckling rodents have been excluded from the requirements because of potential cannibalization by the mother. The same information needed to specifically identify each animal is required on the outside of housing containers or cages. Such identification should substantially reduce the possibility for animal mixup. Because of the varied nature of the tests conducted and the test systems used, the manner of identification is left to the discretion of the testing facility.

The Commissioner advises that whenever a study requires that animals be removed from and returned to their home cages, there is a potential for mixup. Thus, if a single-dose or short-term study requires such manipulations, the animals shall receive appropriate identification.

Because the requirement for unique identification has been deleted, the concerns expressed regarding cost, injury to the animals from various

identification systems, and the effects of dyes or tattoos are no longer germane.

158. Two comments questioned whether the study director could in practice assure unique identification as proposed in § 3e.90(e), without direct observation.

The requirement has been deleted, along with the requirement for unique identification.

159. Two comments requested deletion of the last sentence of proposed § 3e.90(e) regarding the identification of specimens.

The Commissioner concludes that proper specimen identification is an integral part of proper study conduct, but that the requirement more properly belongs under standard operating procedures. Consequently, § 58.81(b)(8) now incorporates this provision.

160. One comment inquired whether, in the event animals of the same species in different tests were in the same room, FDA would require identification of all compounds. This, it was felt, would raise confidentiality questions for a contract testing facility.

The Commissioner advises that the use of coding to identify test or control articles is not precluded by § 58.90(e). The concluding phrase, "to avoid any intermixing of test animals," was deleted as redundant.

161. Proposed § 3e.90(g) required comparison of cage and animal identification for each transfer, procedures for verification, and written permission of the study director for location transfer. Seventeen comments objected to part or all of these requirements as vague, burdensome, unnecessary, and redundant.

The Commissioner agrees, and the paragraph is deleted. Procedures for the transfer and proper placement of animals are required as standard operating procedures in § 58.81(b)(12).

162. Several comments claimed that the requirements of proposed § 3e.90(h), redesignated § 58.90(f), were redundant in view of the requirement for standard operating procedures in § 58.81. Other comments stated that the incorporation of guidelines by reference was inappropriate.

The Commissioner concludes that the requirement that animal cages, racks, and accessory equipment be cleaned is appropriately included in this section even though there is some overlap with the language of § 58.81, standard operating procedures. The reference to other agency guidelines has been deleted.

163. Three comments asserted that sanitization should not always be done, because it could in certain cases interfere with the conduct of the study.

The Commissioner agrees and points out that the language in redesignated

§ 58.90(f) permits cleaning and sanitization at appropriate intervals. The section now reads: "Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals."

164. Many comments objected to proposed § 3e.90(i), redesignated § 58.90(g), which requires periodic analysis of feed and drinking water for "known interfering contaminants." Certain of these comments requested clarification or deletion, or expressed concern about the costs involved. Others argued that the use of positive and negative controls would accomplish the intent of the requirement, or that certificates of analysis from local water supply authorities and feed manufacturers should be permissible. Finally, a few comments said analysis of feed and water should only be required when there is reason to believe that a particular contaminant may have an effect on the study, and comments said the analysis requirements should be specified in the protocol.

Most of the objections raised against the analytical requirements of the section were based on misinterpretation of such requirements. The intent of the Commissioner was to require analysis for contaminants known to be capable of interfering with the nonclinical laboratory study and reasonably expected to be present in the feed or water, and not to require analysis of feed and water for all contaminants known to exist. Certain contaminants could affect study outcome by masking the effects of the test article, as was observed in recent toxicological studies of pentachlorophenol and diethylstilbestrol, in which the feeds used as carriers for the test articles were found to contain varying quantities of pentachlorophenol and estrogenic activity, respectively, that invalidated these studies by producing erratic results. The use of positive and negative controls in these examples was insufficient to compensate for the variability in contaminant content. Therefore, the Commissioner agrees, with the comments that suggested that analysis of feed and water only be done when there is reason to believe that a particular contaminant may have an effect on the study, and may be present in the feed or water, and the language of both redesignated § 58.90(g) and § 58.120(a)(9) have been revised to make this clear. This clarification of the regulations should allay the concerns of those comments relating to certificates of analysis, costs, and precise definition of impurities. Acceptable contaminant limits must be specified by the protocol (§ 58.120(a)(9)), and should be determined at the time the protocol is developed, taking into account the scientific literature, the availability of suit-

able analytical methodology, and the practicability of controlling the level of the contaminant.

165. One comment suggested additional requirements for, e.g., analysis of nutrients and reserve samples of feed at the testing facility.

Nutrient analysis should be addressed by the facility's standard operating procedures. Requirements for reserve samples of test or control articles/carrier mixture (e.g., feed) are set forth in § 58.113(b). The Commissioner concludes that minimum requirements for those items are set forth in the regulation. The regulation does not preclude the setting of additional requirements by the sponsor and/or the testing facility.

166. Proposed § 3e.90(j) would have required feed to bear an expiration date. Twenty-three comments argued that this requirement is of dubious value, is beyond the current state of the art because of varied storage conditions, and that commercially available feed is not expiration dated, making the requirement impractical or impossible.

The Commissioner agrees with these comments, and this requirement is deleted.

167. Several comments argued that the requirement for weekly changes of bedding should be deleted. The comments stated that, in certain cases, weekly bedding changes are contraindicated.

The Commissioner agrees, and the phrase "at least once per week" is removed from § 58.90(h), which now reads, "Bedding * * * shall be changed as often as necessary to keep the animals dry and clean."

TEST AND CONTROL ARTICLES

TEST AND CONTROL ARTICLE CHARACTERIZATION

168. One comment suggested that § 58.105 be deleted; another suggested that the entire subpart be condensed; and three comments suggested that the section is not generally applicable to nonclinical device studies, particularly with reference to such terms as "identity, strength, quality, and purity."

The Commissioner does not agree that the section should be deleted. Its purpose is to assure that the article being tested has been thoroughly characterized or defined and that either the sponsor or the testing facility has a thorough understanding of what is being tested. The Commissioner agrees that the subpart should be condensed and has shortened it. Section 58.105(a) is modified by the inclusion of the sentence "the identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article." This addition provides for charac-

terization of various products, including devices in terms suited to their identity or uniqueness.

169. One comment argued that the requirement that "other substances contained in the test and control substances" be accounted for, as proposed in § 58.105(a), was vague.

By this provision the Commissioner intended to indicate the need to identify and characterize solvents, excipients, inert ingredients and/or impurities that might be part of the test substance. Because these materials are included by definition in the term "test article," the Commissioner has determined that the original language was unnecessary and has deleted it.

170. Three comments sought definition of the word "batch" as used in § 58.105(a).

The term "batch" is now defined in § 58.3(n).

171. Seventeen comments on § 58.105(a) stated that because some control or reference articles might be a competitor's or a supplier's product, the assay and method of synthesis might not be available or might be confidential.

The Commissioner concludes that, in those cases where a competitor's or supplier's product is used as a control article, such products will be characterized by the labeling and no further characterization is necessary.

172. One comment stated that the testing facility should not be responsible for identity, strength, quality and purity and that this responsibility should rest with the sponsor. This comment also suggested that the requirement, as written, would inhibit the conduct of blind studies.

The Commissioner concludes that it is the responsibility of testing facility management to assure that the requisite tests have been done, either by the sponsor or by the test facility (see § 58.31(d)). In those cases where a testing facility is unable to perform the characterization test or is performing blind studies, the sponsor should perform the required testing and notify testing facility management that the characterization of the test or control article has been performed. The section, as revised, does not inhibit the conduct of blind studies; it does not require that the sponsor give the characterizing information to the testing facility, only that the sponsor notify the testing facility that the required characterization has been done.

173. One comment suggested that the requirements of § 58.105 should only apply if the integrity of the study is threatened, and another suggested that any contaminants in a test or control article should be evaluated only with respect to their impact on study validity.

The Commissioner does not agree that the requirement should be so limited. Thorough characterization of the article under test is essential because the results of the test may be compromised by possible contamination. Only by knowing the identity and quantity of the components can one predict their effect on the study. The evaluation of the impact of test and control article contaminants on the validity of the study is an important part of the thorough characterization of the test and control articles.

174. Thirteen comments suggested that characterization of the test article be permitted during the study, after its completion, or left to such time as specified in the protocol.

The Commissioner concludes that characterization of the test or control article should be determined before the initiation of the study in order to provide a means of controlling variations from batch to batch as well as to make certain that the test article meets the specifications of the protocol. As previously stated, a thorough understanding of the nature of the test article is a basic requirement for assuring the absence of contaminants that may interfere with the outcome of the study. When the stability of the test and control articles has not been determined before initiation of the study, the regulation requires periodic reanalysis of each batch of test and control articles as often as necessary while the study is in progress.

175. One comment stated that the phrase "verifying documentation" in § 58.105(a) was not clear.

The Commissioner has determined that the phrase is not needed, and § 58.105(a) is revised to delete it.

176. Seven comments suggested that stability studies required by § 58.105(b) may not always be necessary; three comments suggested that common vehicles and placebo controls, such as water, should be omitted from stability studies.

Some degree of instability may be associated with every test article that might be the subject of nonclinical laboratory study. The Commissioner concludes, therefore, that stability information must be included as part of the information upon which the agency bases a decision regarding the safety of the article. If the stability of common vehicles is generally recognized and can be documented, stability testing is not required.

177. Twelve comments suggested that the term "production" in proposed § 3e.105(c) should be deleted or changed by substitution of other terms such as "approved" or "released," stating that the use of the word was confusing. Several other comments stated that the requirement that test and control substances be de-

rived from the smallest number of production batches consistent with their stability was not always possible or necessary.

The Commissioner agrees that the section was confusing and finds that the requirement is adequately covered by § 58.105(a). The word "batch" has been defined in § 58.3(n), and proposed § 3e.105(c) has been deleted.

178. One comment suggested that the test and control articles should be derived from a large number of batches to increase the probability that test and control articles are representative.

The Commissioner agrees that, in some cases, combining representative samples of test or control articles from various production sources or lots to form a batch may be desirable. Where this is done, however, the resulting batch, rather than the individual samples, must be characterized in accordance with § 58.105(a).

179. Eight comments on § 58.105(d) suggested that the requirement for reserve sample retention be restricted to those substances whose stability had not been previously determined. Another comment suggested that the section seems to require that a reserve sample of water be retained if water is used as the control article, and another comment suggested that the retention of a reserve sample should be left to the discretion of the sponsor.

The Commissioner does not agree that the decision to retain a reserve sample should be at the discretion of the sponsor. Maintaining a reserve sample is necessary to provide independent assurance that the test system was exposed to the test article as specified in the protocol. Reserve samples need not be reanalyzed routinely if the stability of the test or control article is well established. If, however, the results of a study raise questions as to the composition of the test or control article, retention of reserve samples allows resolution of the question. Retention of a reserve sample of water is required when it serves as the control article in a nonclinical laboratory study.

180. Eight comments on § 58.105(d) suggested that containers should be comparable rather than identical to maintain approximate ratio of mass of article to container volume.

Reserve samples should be stored in containers and under conditions that maximize their useful life. The specifications for containers are deleted from § 58.105(d), however, and are now left to the discretion of the study director.

181. Six comments said § 58.105(d) duplicated §§ 58.105(b) and 58.113(a)(2); three said that the requirement that the reserve sample be analyzed at the time the batch is depleted, at the termination of the

study, or at the expiration date may result in unnecessary testing. One comment suggested that a portion of the remaining article should be tested rather than testing the reserve sample.

The Commissioner agrees that the requirement for routine reanalysis of all test or control articles is unnecessary where stability characteristics have been well established, and this requirement has been deleted. The Commissioner does not agree that the cited sections duplicate one another. Section § 58.105(b) concerns the stability of test and control articles in a carrier mixture. But § 58.105(d) concerns reserve samples of test and control articles.

182. A number of comments on proposed § 3e.105(f) sought clarification of the requirements, definition of the term "quarantine," and deletion of the requirement to reanalyze batches returned from distribution.

The Commissioner has examined the provision as proposed and has found that the intent is achieved by the provisions of § 58.107 (test and control article handling). Proposed § 3e.105(f) has, therefore, been deleted.

TEST AND CONTROL ARTICLE HANDLING

183. One comment asserted that § 58.105 covered the specifics for handling test and control substances and that § 58.107 should be deleted.

The Commissioner disagrees with the assertion that § 58.107 repeats § 58.105. The provisions of § 58.105 apply to the characterization of test and control articles and their storage prior to use. Section 58.107 sets forth provisions for the handling and distribution of test and control articles during the course of a nonclinical laboratory study. The purpose of this section is to provide further mechanisms to assure that test and control articles meet protocol specifications throughout the course of the study, and that test article accountability is maintained.

184. Other comments argued that the language of § 58.107 should be modified and that, as written, the section was impractical.

The Commissioner does not agree that the requirements are impractical. The section has, however, been edited for clarity. Section 58.107(a) now reads, "There is proper storage." Because contamination is only one of the consequences that may result from improper handling during distribution, the Commissioner has revised § 58.107(b) to read: "Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage."

MIXTURES OF ARTICLES WITH CARRIERS

185. Many comments stated that the requirements of § 58.113 should only apply to certain types of studies, such as long term feeding studies, or should apply only in cases where problems of instability might result from mixing the test article with a carrier.

The Commissioner does not agree. The need to know that the test system is being exposed to the amounts and types of test and control articles that are specified in the protocol is common to all types of studies. The effect of mixing on the concentration and stability of the test or control article in the mixture cannot be predicted beforehand.

186. Six comments stated that the requirement that each batch of a test or control article that is mixed with a carrier be tested for uniformity of mix, stability, and release, as proposed in § 58.113, was excessive.

The Commissioner has reviewed the reasons advanced by the comments and has deleted the "for each batch" requirement. Once the uniformity of the mixture has been established for a given set of mixing conditions, it is not necessary to establish the uniformity of each subsequent batch that is mixed according to the same specifications. Similar considerations apply to stability testing. Section 58.113(a)(1) introductory text and (a) now read: "For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted: (1) to determine the uniformity of the mixture and to determine, periodically, the concentration of the test or control article in the mixture." The sentence, "[I]f the nonclinical study is to be performed as a blind study, enough individual samples of the mixture shall be returned to the sponsor for analysis," has been deleted. The requirement for analysis of test or control article mixtures is adequately addressed by the revised language of § 58.113(a)(1). The mechanism of satisfying the requirement is left to the testing facility. Blind studies are discussed in paragraph 172 above.

187. One comment stated that the possibility of administration by other than the oral route should be considered.

The Commissioner agrees, and reference to the route of administration is removed.

188. Several comments said the acute and subacute toxicity studies are often conducted before there is extensive knowledge about a drug's stability and that in such cases the drug might be prepared daily. In addition, it was suggested that § 58.113(a)(2) allow for concurrent stability studies.

The Commissioner agrees with the comment and has revised the regula-

tion to allow concurrent studies of stability to proceed with the ongoing nonclinical laboratory study.

189. Three comments on § 58.113 suggested that establishing expiration dates for a substance used up in a week seemed too stringent. Many comments suggested that the expiration dating requirement be eliminated entirely because batch sizes are established so that they will be used up prior to deterioration of the test article.

The Commissioner has considered the comments and has revised, as noted above, the requirement for labeling each batch of test or control article carrier mixture to permit concurrent stability testing. The Commissioner declines to eliminate entirely the requirement for listing of expiration dates. Expiration dates should be used, when known, to minimize the possibility that subpotent, unstable, or decomposed test or control article carrier mixtures will be used. New § 58.113(c) requires that, where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

190. Many comments on proposed § 3e.113(a)(3) stated that the requirement for tests to determine the release of the test or control substance from the carrier needed to be clarified, might be impossible to do, and were not always necessary.

The Commissioner has reviewed the comments and the section and finds that such testing should be adequately addressed by the protocol. He has, therefore, deleted the section.

191. Eleven comments suggested that the requirement that reserve samples of each batch of test or control article-carrier mixture be retained was excessive and impractical.

The Commissioner does not agree. Maintenance of reserve samples of these mixtures is necessary for the same reasons that reserve samples of test and control articles themselves are necessary. These reasons are stated in paragraph 179 above.

192. Proposed § 3e.115 incorporated principles set forth in other regulations and has, accordingly, been deleted. (See the discussion in paragraph 3.)

PROTOCOL FOR AND CONDUCT OF A NONCLINICAL LABORATORY STUDY

PROTOCOL

193. Several comments said the protocol requirements of § 58.102(a) were not relevant to specific test articles, e.g., electronic diagnostic instrumentation. Other comments objected to requiring a protocol for short-term studies or for routine tests described else-

where in 21 CFR Chapter I. Additional comments proposed that specific requirements be imposed only where applicable, and one comment said the protocol should focus on what is intended rather than on how the intended result is to be achieved.

The Commissioner has previously discussed the types of tests and the conditions within the scope of Part 58. Because of the broad range of studies covered, specific sections may not apply to all studies. However, the Commissioner declines to exempt short-term studies or routine tests from these requirements. Any study which qualifies as a nonclinical laboratory study is subject to the requirements. The good laboratory practice regulations are both process-oriented and product-oriented, and are designed to ensure, insofar as possible, the quality and integrity of nonclinical laboratory data submitted to FDA in support of regulated products. The Commissioner recognizes that some of the requirements of this section have often not been traditionally included in a protocol. He has nonetheless concluded that the requirements are essential to ensure that all operations needed to fulfill the objectives of a study are performed and that the complete list of information required by this section is necessary to ensure that deviations, should they occur, are readily apparent.

194. One comment asked what was meant by "all methods" in § 58.120; one suggested deletion of the word "approved" to describe the protocol; and another suggested that reference to statistical methods in § 58.120(a) be deleted and that a new paragraph on statistical methods be added to the list of information required.

"All methods" refers to all operations necessary to achieve the objectives of the study, e.g., analytical methods, randomization procedures, etc. If such methods are from published sources, citation of the source would fulfill this requirement. If the methods are not from published sources, full descriptions would need to be included in the protocol. The word "approved" is retained to emphasize that a sponsor or testing facility should have a mechanism for evaluation and approval of initial protocols and all amendments. A new paragraph (a)(16) is provided to emphasize the need to consider statistical methodology in preparing a protocol.

195. Ten comments objected to the inclusion, in proposed § 3e.120(a)(3), of stability methodology as a protocol requirement because such methodology may not have been developed before the study was begun. Another comment suggested deletion of this requirement as not relevant to a proto-

col, while three comments suggested revision.

The Commissioner recognizes that stability data may not be available when a study is initiated, and this requirement is deleted from the section. The Commissioner emphasizes, however, that determination of the stability of the test and control articles is a responsibility of the study director, that determination of the stability of the articles per se is required under § 58.105(b), and that determination of the stability of the article/carrier mixes is required under § 58.113.

196. Numerous comments on proposed § 3e.120(a)(4) objected to the listing of the names of laboratory assistants and animal care personnel in the protocol because these jobs are subject to constant turnover or periodic rotation.

The Commissioner agrees that laboratory assistants and animal care personnel need not be identified in the protocol. The list of personnel required to be named is transferred to § 58.185(a)(12).

197. One comment proposed that listing the name of the sponsor and name and address of the testing facility required by § 58.120(a)(3) be restricted to studies done under contract.

The Commissioner does not agree with restricting this requirement to studies done under contract because a testing facility, though a division of the sponsor, may have a specific designation and a location different from the sponsor's, and this information is necessary to determine the exact location of the study.

198. Numerous comments on § 58.120(a)(4) objected to specifying starting and completion dates in the protocol because changing priorities may make such specification impractical. Another comment proposed deletion of the requirement for dates as not relevant to a protocol.

Changing priorities may cause changes in starting dates. For this reason the requirement calls for the proposed dates. If the actual dates differ from the proposed dates, the change should be reflected in a protocol amendment. The dates may be needed in the reconstruction of the study.

199. Ten comments on proposed § 3e.120(a)(7) objected that the proposed date for submission of the final study report to management or to the sponsor was not relevant to a protocol, and one requested a definition of the term "completion date."

The Commissioner agrees that the proposed submission date is not relevant, and the provision is deleted.

200. Numerous comments on § 58.120(a)(6) suggested requiring age of the test system only where applica-

ble or substituting age range for age. Several objected to the requirement for justification for selection of the test system as not relevant to protocol requirements. Additional comments proposed that the requirement for justification be limited to nonroutine systems.

The Commission agrees that age of the test system may not always be critical, and § 58.120(a)(6) now requires number, body weight range, sex, source of supply, species, strain and substrain, and age of the test system only "where applicable." The Commissioner does not agree that justification for selection of the test system is not relevant to a protocol or should be limited to nonroutine systems. Such justification is an integral and essential part of every protocol and to emphasize its importance, the Commissioner is establishing a separate paragraph for this requirement, § 58.120(a)(5).

201. Several comments on § 58.120(a)(8) (proposed § 3e.120(a)(10)) objected that the method of randomization was not relevant to the protocol and suggested requiring justification for the selected method only when nonroutine methods are selected; four comments said justification of the method of randomization is unnecessary; and one comment proposed revised language regarding method of randomization.

The Commissioner finds that the method of randomization or other methods of controlling bias are relevant and are essential parts of a protocol, whether the methods used may be described as routine or nonroutine. The suggested revision is adopted in part, and § 58.120(a)(8) now reads: "A description of the experimental design, including the methods for the control of bias."

202. One comment said a description of the diet used in the study (proposed § 3e.120(a)(11), now § 58.120(a)(9)) was unnecessary unless the diet was unusual. The comment further said that the necessity for including solvents and emulsifiers was questionable because these might not be known at the time the protocol is written.

The Commissioner advises that the phrase "and/or identification" in § 58.120(a)(9) permits a commercial animal diet to be identified by its name. The need for using solvents or emulsifiers may not be known when the protocol is written; however, when this information is available and the solvents, etc., are selected, this fact should be reflected in a protocol amendment.

203. Nine comments pointed out that the degree of absorption (proposed § 3e.120(a)(14)), now § 58.120(a)(12)) is usually unknown at the time of the preparation of the protocol.

The Commissioner recognizes that absorption studies may be conducted concurrently with or as part of the nonclinical laboratory study and points out that the requirements of § 58.120(a)(12) can be fulfilled by amending the protocol.

204. Nine comments suggested deletion of the requirement that the protocol include the records to be maintained (proposed § 3e.120(a)(16), now § 58.120(a)(14)) because this duplicates the requirements under another provision of the regulation.

The Commissioner concludes that the protocol should include a plan identifying the records to be maintained and, therefore, does not agree that § 58.120(a)(14) should be deleted.

CONDUCT OF A NONCLINICAL LABORATORY STUDY

205. Several comments objected to the § 58.130(c) requirement that specimens be identified. Three comments proposed revisions to eliminate the list of specific items (test system, study, nature, date of collection) included for identification of specimens. Numerous comments objected to the identification system as overly restrictive, stating that a coding system should be permitted.

The Commissioner rejects the suggested modifications because the requirements are designed to preclude error. The specific items required to identify a specimen are the minimum necessary to prevent mixup of specimens and permit orderly storage. The Commissioner does not agree that this system is overly restrictive because it does not preclude a coding system.

206. Numerous comments objected to the requirement, in § 58.130(e), for recording data in bound books with prenumbered pages as costly, time-consuming, overly restrictive, and difficult for long-term studies. Six were concerned that much information is too voluminous to be recorded directly and that reference to other documents should be permitted to justify changes, and two comments objected to recording "dictated observations" in ink.

The Commissioner agrees that the requirement for bound books is too restrictive in view of both the variety of data recording procedures that can be used in nonclinical laboratory studies covered by this part and the many ways in which data are generated and collected for these studies. He is, therefore, revising the section. As revised, § 58.130(e) does not preclude reference to other documents if the documents are clearly identified and available. The requirements of the section can be met by maintaining the dictation media or an exact transcription.

207. Three comments proposed that § 58.103(e) be revised to reflect the

three types of computer entries, i.e., direct on-line recording, input from computer readable forms, and input transcribed from recorded raw data. An additional comment suggested revised language to achieve this purpose; and two comments stated that computer printouts of interim display data need not be maintained when the data are wholly contained in subsequent iterations.

The revised wording of § 58.130(e) is equally applicable to the various forms of computer data entries. The Commissioner advises that where the data for computer input are in machine-readable form, such as marketed-sense cards, or are transcribed from recorded raw data, the machine-readable forms or the recorded raw data would constitute raw data within the definition of this part. Where input is via direct on-line recording, the magnetic media and the program would constitute raw data within the meaning of this part.

208. Three comments objected that a daily signature and date for each entry would be burdensome in studies involving daily measurements on each animal.

Section 58.130(e) does not require signing and dating of every individual item recorded. An entry can consist of several observations of several animals made by the same person.

209. Three comments suggested deletion of proposed § 3e.130(f), which required the review of all recorded data, because this duplicated the function of the study director.

The Commissioner agrees that these requirements are adequately addressed by § 58.33(b), and the paragraph is deleted.

RECORDS AND REPORTS

REPORTING OF NONCLINICAL LABORATORY STUDY RESULTS

210. Seven comments said the requirement that the final report include all raw data and calculations proposed in § 3e.185(a)(3) is not practical and that a recapitulation should be adequate.

The Commissioner agrees, and the requirement that all raw data be included in the final report is deleted.

211. Two comments on § 58.185(a)(3) stated that the scope of the term "method" was not clear.

The Commissioner advises that "method" does not mean that either the actual calculations or a step-by-step reiteration of the process be included. The name of the method, the description of the method, or a reference to an article or test describing the method will be sufficient.

212. Several comments on § 58.185(a)(4) stated that the final report should provide only a reference to the information on "strength, qual-

ity, and purity" rather than the actual values for those characteristics.

The Commissioner does not agree. The final report should include actual values for all characteristics required for proper identification. Because the actual values for strength, quality, and purity are not, in every case, sufficient for adequate identification, the word "quality" has been stricken and the words "and composition or other appropriate characteristics" have been added. The additional language will permit the use of any characteristic which facilitates identification of the test and control article.

213a. Several comments on § 58.185(a)(5) stated that the requirement that stability of the test and control articles be described should be narrowed.

The Commissioner finds that stability information must be submitted as part of the final report. The extent of stability testing required by these regulations is discussed at paragraphs 176, 185, 186, and 189 above.

b. Comments on proposed § 3e.185(a)(8) (now § 58.185(a)(7)) requested that the words "appropriate and necessary" be inserted following the words "procedure used", for identifying the test system.

The Commissioner is modifying § 58.185(a)(7) to require reporting such details where applicable.

214. Seven comments on § 58.185(a)(12) protested the requirement that the final report include reports of each of the individual scientists or other professionals involved in the study.

The Commissioner concludes that the individual reports are required to assure that the final results reported accurately reflect the findings of the individual scientists.

215. A number of comments on § 58.185(a)(3) objected to reporting the location of the raw data in the final report.

For the purpose of information retrieval, the Commissioner is of the opinion that the location of the raw data should be specified.

216. The Commissioner advises that the list of personnel required to be named in the final report as specified in § 58.185(a)(12) has been broadened to include all professionals. (See paragraph 196 above.)

STORAGE AND RETRIEVAL OF RECORDS AND DATA

217. Several comments requested revision and clarification of "other information" in § 58.190(a).

The phrase "and other information" is deleted because it is subsumed by the specific requirements for documentation.

218. Five comments requested clarification of the term "specimen" as used in § 58.190(b).

The term "specimen" is defined in § 58.3(j) and means any material derived from a test system for examination or analysis. This includes wet specimens, histological blocks, and slides that yield information pertinent to the outcome of the study. Such specimens are required to bear sufficient labeling to permit identification and expedient retrieval.

219. Several comments stated that the prohibition against "intermingling" of specimens was unnecessary if specimens are properly labeled and indexed.

The Commissioner agrees and finds that the storage requirements are adequate to achieve their purpose without any further prohibitions. The reference to intermingling of samples is, therefore, deleted.

220. Seven comments said proposed § 3e.190(c) was unclear or redundant and required the maintenance of unnecessary duplicative files by both the testing facility and the sponsor.

The Commissioner agrees with the comments, and the paragraph is deleted.

221. A number of comments requested that § 58.190(c) provide that more than one person be permitted to be responsible for the archives.

The Commissioner reaffirms the need for one individual to be accountable for the maintenance and security of the archives to prevent access by unauthorized personnel. Such access could lead to the loss of, or damage to, records and specimens required to be maintained by these regulations. This provision does not preclude delegation of duties to other individuals who may help maintain the archives.

222. Comments on § 58.190(e) suggested that coding of archival contents should be allowed and objected that the section would require four-way indexing.

The paragraph is revised for clarity. As revised, the use of a coding system is permitted; however, the cross-reference indexing system is retained as a requirement.

223. Section 58.190(g) is deleted because the inspection requirements are adequately addressed by § 58.15.

RETENTION OF RECORDS

224. Several comments stated that the proposed record retention requirements were inconsistent with those previously established.

A new paragraph (a) is added to § 58.195 to make it clear that the record retention requirements of this section do not supersede those of any other regulations in this chapter.

225. Several comments pointed out that IND's are not "approved" and

asked that the record retention requirements for IND's be clarified.

The Commissioner agrees that the record retention requirements, as they apply to both IND's and IDE's, need clarification. In addition to the fact that IND's are not, in a technical sense, "approved," the Commissioner has considered the fact that when either an IND or an IDE is submitted to the agency, the application may contain voluminous data collected over a number of years. It was not the intent of these regulations that such supporting IND or IDE data be destroyed after 2 years because not all studies submitted at the time of filing may be of interest to the agency until several years after submission. Therefore, a new sentence is added to § 58.195(b)(1), which states that the 2-year retention requirement does not apply to studies supporting notices of claimed investigational exemptions for new drugs (IND's) or applications for investigational device exemptions (IDE's). These records are governed by § 58.195(b)(2) and shall be retained for at least 5 years. This additional language clarifies both agency policy and current scientific practice which is, in most cases, to maintain such study records far longer than 5 years.

226. One comment said the variable record retention periods are unworkable, and another said records should be maintained as long as the public is exposed to a chemical.

The record retention period represents the minimum deemed appropriate. For uniformity, all records may be retained for 5 years. Longer retention periods are unnecessary because each nonclinical testing facility will be inspected every 2 years. Studies conducted at facilities that are in substantial compliance with these regulations will be presumed to be valid. When significant deviations are discovered, steps will be taken to validate individual studies before the record retention period expires.

227. Twenty-three comments on § 58.195(b)(3) objected to the record retention requirement as it applies to terminated or discontinued studies, stating that the requirement goes beyond the intent expressed in the definitions or that FDA lacks the authority to require that such studies be retained.

The Commissioner finds that such studies are frequently capable of yielding information applicable to evaluations of related compounds. In the interest of the public health, all such data derived from studies originally intended to be submitted to the agency should be available to the agency. This is particularly important when studies are terminated because of preliminary findings that the test article causes adverse effects at such low levels that

any safe use of the article is precluded. The general question of FDA's authority is discussed in paragraph 5 above.

228. With respect to retention of appropriate samples, including wet specimens, several comments on § 58.195(c) requested that the regulations specifically set forth conditions of storage. Others felt that this requirement would be of doubtful value, and several were concerned that the retention period not exceed that which could adversely affect sample integrity.

The Commissioner states that it would be impractical to attempt to specify the specific storage conditions for sample retention. This should be left to the judgment of the testing facility. It is essential as a check on recorded observations that, wherever possible, samples be retained for confirmation of findings. Such samples should be retained for the minimum period specified in the regulations. The regulation clearly states that fragile samples shall be retained only so long as the quality of the preparation affords evaluation.

229. Three comments on § 58.195(e) objected to archive retention of curricula vitae and job descriptions of all personnel involved in the study.

Section 58.195(e) is revised to permit this information to be retained as part of the testing facility employment records.

230. One comment on § 58.195(f) stated that equipment records should be maintained in an independent log rather than maintained as part of each study.

The Commissioner advises that the language of the section does not preclude such an approach. Records of maintenance and calibration of equipment may be kept in a repair manual or on a tag affixed to the instrument. The reference to cleaning records is deleted.

DISQUALIFICATION OF TESTING FACILITIES

PURPOSE

231. Many comments were received concerning the general concept and purpose of disqualification.

The Commissioner believes that many of these comments were based, at least in part, on misunderstanding of the frequency with which disqualification might be used. The Commissioner believes disqualification is an important alternative to rejection of specific studies and legal prosecution because it can reduce by consolidation the number of FDA investigations and administrative proceedings that might be required if FDA acted only on a study-by-study basis. To clarify the agency's intent regarding the disqualification mechanism and to allay fears that this sanction might be abused,

the Commissioner is revising Subpart K of the regulations to define more clearly the grounds for disqualification.

231. Section 58.200(a) has been revised to clarify the purposes of disqualification. The first purpose stated in the section is to permit FDA to exclude from consideration any completed studies conducted by a testing facility which has failed to comply with good laboratory practice requirements until it can adequately be demonstrated that the noncompliance did not occur during, or did not affect the validity of data generated by, a particular study. Thus, for studies completed before disqualification, the order of disqualification creates a rebuttable presumption that all studies previously conducted by the facility are unacceptable. Such a study may be accepted, however, upon presentation of evidence demonstrating that the noncompliance which resulted in the disqualification did not affect the particular study. The second purpose set forth in the revision of § 58.200(a) is to exclude studies completed after the date of disqualification from consideration until the facility can satisfy the Commissioner that it will conduct studies in compliance with the regulations. (See also the discussion in paragraph 241.)

GROUND FOR DISQUALIFICATION

232. Many comments argued that the disqualification provisions appeared to be overly harsh, arbitrary, and ambiguous.

To clarify the agency's intent, the Commissioner is revising the section. The primary function of the agency's regulation of nonclinical laboratory testing is to assure the quality and integrity of data used in making judgments about the safety of products regulated by the agency. The grounds for disqualification are based on those types of noncompliance that significantly impair achievement of those objectives. Proposed § 3e.202(a) through (p) is deleted, and new § 58.202(a) through (c) clarifies the policy that a testing facility may be disqualified only if the Commissioner finds all three of the following: (1) That the testing facility failed to comply with one or more of the standards set forth in Part 58 or in any other FDA regulations regarding standards for nonclinical testing facilities (e.g., any supplemental requirements in the IND or IDE regulations); (2) that the noncompliance adversely affected the validity of the data produced by the study; and (3) that other lesser regulatory actions, such as warnings or rejection of data from individual nonclinical laboratory studies, have not been or probably will not be adequate to achieve compliance. This

approach will assure that the sanction will not be used in trivial situations, but will be invoked only when the violation has compromised the integrity of a study. It further requires the Commissioner to consider the availability and probable effectiveness of lesser sanctions as an alternative to disqualification. It would not, however, preclude disqualification without prior warning.

As pointed out in the preamble to the proposed regulations, the provisions for disqualification are not to be interpreted as either the exclusive or primary administrative action for non-compliance with good laboratory practice. Disqualification is designed to provide FDA with an enforcement tool that is more efficient and effective than a study-by-study review when it becomes apparent that a testing facility is not capable of producing accurate and valid test results. The disqualification of a nonclinical testing facility will be reserved for the rare case when the rejection of a particular study is an inadequate regulatory response. The testing facility and/or the sponsor of the nonclinical laboratory study may also be prosecuted for violations of Federal criminal laws, including section 301(e) of the Federal Food, Drug, and Cosmetic Act (failure to make a report required under certain other sections of the act, because a grossly erroneous or inadequate report does not fulfill the statutory obligation) and 18 U.S.C. 1001 (submission of a false report to the government). Even where the testing facility is not under a direct statutory obligation to submit information to FDA, and in fact does not send data to the agency but merely transmits them to the sponsor, the facility is likely to be aware that FDA will be the ultimate recipient. In such cases, it may be liable for aiding and abetting in the violation (18 U.S.C. 2) or for causing the violation to be made by a third party.

233. Two comments stated that the disqualification regulation seemed to apply only to private firms.

This interpretation is incorrect. The preamble to the proposed regulations makes clear the policy that the good laboratory practice regulations are to apply to any institution that generates or otherwise prepares safety data for submission to FDA. Included in that definition, to the extent that they prepare safety data to be submitted to FDA in support of petitions for regulated products, are, for example, veterinary and medical clinics, universities and State experimental stations, and State and Federal Government research laboratories. Accordingly, disqualification provisions apply equally to all facilities that prepare safety data for submission to FDA. The lan-

guage regarding the intended use of sanctions is incorporated into § 58.202(c).

NOTICE OF AND OPPORTUNITY FOR HEARING ON PROPOSED DISQUALIFICATION

234. Several comments stated that the disqualification process, as proposed, would violate due process, deny a formal hearing, and deny a right of appeal to the courts.

The Commissioner advises, and the revisions to § 58.202 make clear, that the disqualification procedure will not be invoked for minor violations of the regulation. In addition, § 58.204 provides that a regulatory hearing may be conducted in accordance with 21 CFR Part 16. Such a hearing provides all the safeguards essential to due process. See also the *FEDERAL REGISTER* of 40 FR 40713 et seq. (preamble to Subpart F of 21 CFR Part 2, recodified as 21 CFR Part 16—Regulatory Hearing Before the Food and Drug Administration; section 201(y) of the act (21 U.S.C. 321(y)) (procedural requirements of an "informal hearing"); *Goldberg v. Kelly*, 397 U.S. 254 (1970). Judicial review of final administrative action is provided by the Administrative Procedure Act (5 U.S.C. 701 et seq.). See also § 10.45 *Court Review of final administrative action; exhaustion of administrative remedies* (21 CFR 10.45); and 40 FR 40689-40691 (preamble to procedural regulations, § 2.11 (recodified as 21 CFR 10.45)).

235. Several comments expressed the concern that any regulatory hearing conducted under 21 CFR Part 16 should provide for the confidentiality of all data on which the hearing is based.

The Commissioner advises that § 16.60(a) (21 CFR 16.60(a)) provides adequate safeguards when required to maintain the confidentiality of commercial information.

236. One comment stated that if notice for such a hearing should be mailed to a facility, more than 3 days should be allowed for a facility to be able to prepare itself to come to a meeting.

The Commissioner finds that the provisions of § 16.22 (21 CFR 16.22) provide adequate flexibility for any party responding to a notice of opportunity for a hearing. See also the comments addressed to 21 CFR 52.204, set out in the preamble to the proposed regulations on obligations of sponsors and monitors, published in the *FEDERAL REGISTER* of September 27, 1977 (42 FR 49619).

237. One comment suggested that § 58.204 include a provision specifying that a sponsor be allowed to intervene in the hearing process when a notice of opportunity for a hearing has issued to a testing facility that is per-

forming studies under contract for the sponsor.

Inasmuch as the disqualification process in such a case is directed at the testing facility rather than the sponsor and inasmuch as the alleged violations involved would be those of the testing facility, the Commissioner finds that intervention by a sponsor (or, in many cases, multiple sponsors) would serve no useful purpose. As noted in the preamble to the proposed regulation (41 FR 51218), a sponsor who wishes to contest a finding that a particular study or studies is or are inadequate will be provided an opportunity to do so by the procedures for denying or withdrawing the approval of an application for a research or marketing permit.

238. Concern was also expressed that a reasonable time be provided to allow a sponsor to conduct a new test prior to termination or withdrawal.

The Commissioner emphasizes that in those cases in which a safety decision has been based on data that have subsequently been called into question, protection of the public requires that proceedings be instituted without delay. As previously noted, opportunity to contest a finding that a particular study is so inadequate that it will not support a claim of safety of a product will be provided by procedures set forth in other regulations, e.g., withdrawal of an NDA.

FINAL ORDER ON DISQUALIFICATION

239. Several comments stated that § 58.206 should provide specifically for appeal to the Federal courts following a final decision to disqualify by the Commissioner.

The Commissioner notes that the provisions of 21 CFR 16.120 and 10.45 adequately address this point. These regulations clearly state the provisions that apply to court review of final administrative action.

240. One comment suggested that § 58.206(b) be modified to require that sponsors be notified, when applicable, at the time of issuance of a final order to a testing facility.

The Commissioner advises that such notification, which is discretionary, is expressly provided for in § 58.213(b). Additionally, § 58.206(a) and (b) are revised to reflect the requirement that the Commissioner must make the findings required by § 58.202 before a final order disqualifying a nonclinical testing facility shall issue.

ACTIONS UPON DISQUALIFICATION

241. Several comments objected to the retroactive provisions of § 58.210(a), which state that once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, that contains or relies upon any nonclinical

laboratory study conducted by the disqualified testing facility may be examined to determine whether these studies were or would be essential to a decision.

The Commissioner advises that calling into question studies performed by a subsequently disqualified testing facility does not represent a departure from prior FDA policy in other areas. FDA must make additional inquiries to establish safety any time a question is raised about data previously submitted, regardless of whether a disqualification procedure exists. Section 58.210(a) allows the person relying on the study in question to establish that the study was not affected by the circumstances that led to disqualification. The safety of the public would not be adequately protected were no such validation required when serious questions are raised regarding the adequacy of data upon which regulatory decisions are based.

Section 58.210 is revised by the addition of paragraph (b), which states that no nonclinical laboratory study begun after a facility has been disqualified will be considered in support of any application for a research or marketing permit unless the facility has been reinstated under § 58.219. This addition makes it clear that, in such a case, no subsequent information can be submitted for purposes of subsequent validation. If the facility is reinstated, however, the study might be acceptable to FDA. This provision does not relieve the applicant from any other requirement under FDA regulations that all data and information regarding clinical experience with the article in question be submitted to the agency.

242. Many comments regarding § 58.210 were based on the assumption that the disqualification process might be invoked for a minor violation of the good laboratory practice regulation and stated that calling studies into question based on a minor violation was unreasonable.

As previously discussed, § 58.202 is revised to make it clear that the disqualification process will be reserved for those situations in which lesser sanctions, e.g., rejection of individual studies, will not suffice. Because disqualification will be reserved for use in serious situations, the Commissioner finds that calling into question all studies done before or after disqualification is warranted.

PUBLIC DISCLOSURE OF INFORMATION UPON DISQUALIFICATION

243. Several comments said that proprietary or trade secret documents should not be released. Others urged that disqualification records not be disclosed.

The Commissioner advises that release of all such documents is governed by the provisions of the Freedom of Information Act (5 U.S.C. 552) and 21 CFR Part 20 and need not be separately dealt with in this regulation. Interested parties are referred specifically to Part 20—Public Information (21 CFR Part 20). Section 20.61 (21 CFR 20.61) deals with trade secrets and commercial information and § 20.64 (21 CFR 20.64) deals with investigatory records. The preamble to the public information regulations (39 FR 44602 et seq.) (since recodified as Part 20) discusses these issues at length.

244. One comment on § 58.213 stated that no notification of other government departments or agencies should issue until completion of the judicial process.

The Commissioner disagrees and finds that withholding notification until completion of the administrative process by the agency provides an adequate opportunity for a testing facility to be heard prior to the issuance of any such notification.

245. Another comment stated that because FDA is a Federal agency, notification of State agencies is outside FDA's jurisdiction.

The Commissioner points out that section 705(b) of the act (21 U.S.C. 375(b)) provides for dissemination of information regarding food, drugs, or devices in situations involving imminent danger to health or gross deception of the consumer. In addition, the Commissioner emphasizes that he proposes to notify the States only in those situations for which adequate cause has been established and for which a final order has been issued. Section 58.213(a) is amended to make it clear that such notification shall state that it is given because of the relationship between the testing facility and the person notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified. Additionally, § 58.213 is modified to make it clear that notification of disqualification may be sent by the Commissioner not only to other Federal agencies but to any other person known to have professional relations with the disqualified testing facility. This includes sponsors of studies being performed by the facility.

246. A comment suggested that the scope of notification should be limited to those nonclinical laboratory studies upon which the decision to disqualify was based.

The language of § 58.213 makes it clear that notification may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the

good laboratory practice regulations. The Commissioner finds that, given the expressed purpose of notification, further limitation would be inappropriate.

ALTERNATIVE OR ADDITIONAL ACTIONS TO DISQUALIFICATION

247. One comment on § 58.215 suggested that informal procedures be used prior to the institution of more formal procedures.

The Commissioner notes that this approach was discussed in the preamble to the proposed regulation at 41 FR 51218. Because such informal procedures have, in the past, doubled the time and expense of all involved parties without discernible benefit, the Commissioner has decided not to provide for informal procedures in these regulations.

SUSPENSION OR TERMINATION OF A TESTING FACILITY BY A SPONSOR

248. Many comments on § 58.217 said that the section seemed to be an attempt on the part of FDA to provide legal grounds for the unilateral breaking of contracts between private parties.

The Commissioner finds that the section, as written, was subject to a great deal of misunderstanding. Therefore, the section is revised. The Commissioner advises that nothing in Part 58 is intended to infringe upon or alter the private contractual arrangements between a sponsor and a nonclinical testing facility. A sponsor may terminate a testing facility for reasons of its own whether or not FDA has begun any action to disqualify that facility. Where a sponsor has independent grounds for suspending or terminating studies performed for that sponsor by the facility under contract, the fact that FDA has not itself disqualified the facility may not be raised by the contract facility as a defense against the sponsor.

249. Several comments said notification within 5 days was impractical.

The Commissioner agrees, and the time period is extended to 15 working days.

250. A number of comments said the notification requirement provided a sponsor with an unfair opportunity to impugn a contract facility that would have no opportunity for response.

The Commissioner emphasizes that termination of a nonclinical testing facility by a sponsor should be subject to the contract between the two parties. A nonclinical testing facility, as a party to the contract, may protect itself from unjust termination by the terms of its contract with the sponsor. Remedies for both parties to such a contract may be spelled out in the contract and are governed by principles of contract law. The Commissioner fur-

ther emphasizes that the requirement that a sponsor notify FDA when it has terminated or suspended a testing facility applies only to those cases in which an application for a research or marketing permit has been submitted. Where no application has been submitted, no notification is required.

REINSTATEMENT OF A DISQUALIFIED TESTING FACILITY

251. One comment on § 58.219 expressed concern that when read with § 58.210, it was confusing.

The Commissioner finds that the addition of § 58.210(b) substantially clarifies the status of studies conducted before, during, and after disqualification and that further amendment is unnecessary.

252. A typographical error in the last sentence of § 58.219 has been corrected. The last sentence now reads: "A determination that a testing facility has been reinstated is disclosable to the public under Part 20 of this Chapter."

CONFORMING AMENDMENTS

253. The Commissioner is adding to or revising provisions in the regulations regarding food and color additives, new drugs for investigational use, new drug applications, OTC drug products, antibiotic drugs, new animal drug applications, biological product licenses, and performance standards for electronic products to incorporate appropriate implementing provisions for, and cross references to, Part 58, which is being added by this document. Each of the regulations requires the submission of data which may include nonclinical laboratory studies. The regulations are being revised to require, with respect to each nonclinical laboratory study contained as part of the submitted information, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations. The revisions highlight the fact that although studies not conducted in compliance with the regulations may continue to be submitted to FDA, the burden of establishing that the non-compliance did not affect the quality of the data submitted is on the person submitting the noncomplying study.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as

amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360j, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n)) and under authority delegated to him (21 CFR 5.1), the Commissioner amends Chapter I of 21 CFR as follows:

SUBCHAPTER A—GENERAL

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. Part 16 is amended in § 16.1 by redesignating paragraph (b)(30) as paragraph (c) and by adding new paragraph (b)(30), to read as follows:

§ 16.1 Scope.

(b) * * *

(30) Section 58.204(b) of this chapter, relating to disqualifying a nonclinical laboratory testing facility.

(c) Any other provision in the regulations in this chapter under which a party who is adversely affected by regulatory action is entitled to an opportunity for a hearing, and no other procedural provisions in this part are by regulation applicable to such hearing.

2. Part 58 is added to read as follows:

PART 58—GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

Subpart A—General Provisions

Sec.

- 58.1 Scope.
- 58.3 Definitions.
- 58.10 Applicability to studies performed under grants and contracts.
- 58.15 Inspection of a testing facility.

Subpart B—Organization and Personnel

- 58.29 Personnel.
- 58.31 Testing facility management.
- 58.33 Study director.
- 58.35 Quality assurance unit.

Subpart C—Facilities

- 58.41 General.
- 58.43 Animal care facilities.
- 58.45 Animal supply facilities.
- 58.47 Facilities for handling test and control articles.
- 58.49 Laboratory operation areas.
- 58.51 Specimen and data storage facilities.
- 58.53 Administrative and personnel facilities.

Subpart D—Equipment

- 58.61 Equipment design.

- 58.63 Maintenance and calibration of equipment.

Subpart E—Testing Facilities Operation

- 58.81 Standard operating procedures.
- 58.83 Reagents and solutions.
- 58.90 Animal care.

Subpart F—Test and Control Articles

- 58.105 Test and control article characterization.
- 58.107 Test and control article handling.
- 58.113 Mixture of article with carriers.

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

- 58.120 Protocol.
- 58.130 Conduct of a nonclinical laboratory study.

Subparts H and I—[Reserved]

Subpart J—Records and Reports

- 58.185 Reporting of nonclinical laboratory study results.
- 58.190 Storage and retrieval of records and data.
- 58.195 Retention of records.

Subpart K—Disqualification of Testing Facilities

- 58.200 Purpose.
- 58.202 Grounds for disqualification.
- 58.204 Notice of and opportunity for hearing on proposed disqualification.
- 58.206 Final order on disqualification.
- 58.210 Actions upon disqualification.
- 58.213 Public disclosure of information regarding disqualification.
- 58.215 Alternative or additional actions to disqualification.
- 58.217 Suspension or termination of a testing facility by a sponsor.
- 58.219 Reinstatement of a disqualified testing facility.

AUTHORITY: Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 701(a), 706, and 801, Pub. L. 717, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463, as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360j, 371(a), 376, and 381); secs. 215, 351, 354-360F, Pub. L. 410, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended (42 U.S.C. 216, 262, 263b-263n).

Subpart A—General Provisions

§ 58.1 Scope.

This part prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the Food and Drug Administration, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with this part is intended to assure the quality and integrity of the safety data filed pursuant to sections 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 706, and 801

of the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

§ 58.3 Definitions.

As used in this part, the following terms shall have the meanings specified:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201-902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321-392)).

(b) "Test article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article subject to regulation under the act or under sections 351 and 354-360F of the Public Health Service Act.

(c) "Control article" means any food additive, color additive, drug, biological product, electronic product, medical device for human use, or any other article other than a test article that is administered to the test system in the course of a nonclinical laboratory study for the purpose of establishing a basis for comparison with the test article.

(d) "Nonclinical laboratory study" means any in vivo or in vitro experiment in which a test article is studied prospectively in a test system under laboratory conditions to determine its safety. The term does not include studies utilizing human subjects or clinical studies or field trials in animals. The term does not include basic exploratory studies carried out to determine whether a test article has any potential utility or to determine physical or chemical characteristics of a test article.

(e) "Application for research or marketing permit" includes:

(1) A color additive petition, described in Part 71 of this chapter.

(2) A food additive petition, described in Parts 171 and 571 of this chapter.

(3) Data and information regarding a substance submitted as part of the procedures for establishing that a substance is generally recognized as safe for use, which use results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food, described in §§ 170.35 and 570.35 of this chapter.

(4) Data and information regarding a food additive submitted as part of the procedures regarding food additives permitted to be used on an interim basis pending additional study, described in § 180.1 of this chapter.

(5) A "Notice of Claimed Investigational Exemption for a New Drug," described in Part 312 of this chapter.

(6) A "new drug application," described in Part 314 of this chapter.

(7) Data and information regarding an over-the-counter drug for human

use, submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, described in Part 330 of this chapter.

(8) Data and information regarding a prescription drug for human use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, to be described in this chapter.

(9) Data and information regarding an antibiotic drug submitted as part of the procedures for issuing, amending, or repealing regulations for such drugs, described in Part 430 of this chapter.

(10) A "Notice of Claimed Investigational Exemption for a New Animal Drug," described in Part 511 of this chapter.

(11) A "new animal drug application," described in Part 514 of this chapter.

(12) Data and information regarding a drug for animal use submitted as part of the procedures for classifying such drugs as generally recognized as safe and effective and not misbranded, to be described in this chapter.

(13) An "application for a biological product license," described in Part 601 of this chapter.

(14) An "application for an investigational device exemption," described in Part 812 of this chapter.

(15) An "Application for Premarket Approval of a Medical Device," described in section 515 of the act.

(16) A "Product Development Protocol for a Medical Device," described in section 515 of the act.

(17) Data and information regarding a medical device submitted as part of the procedures for classifying such devices, described in section 513 of the act.

(18) Data and information regarding a medical device submitted as part of the procedures for establishing, amending, or repealing a performance standard for such devices, described in section 514 of the act.

(19) Data and information regarding an electronic product submitted as part of the procedures for obtaining an exemption from notification of a radiation safety defect or failure of compliance with a radiation safety performance standard, described in Subpart D of Part 1003 of this chapter.

(20) Data and information regarding an electronic product submitted as part of the procedures for establishing, amending, or repealing a standard for such product, described in section 358 of the Public Health Service Act.

(21) Data and information regarding an electronic product submitted as part of the procedures for obtaining a variance from any electronic product

performance standard as described in § 1010.4 of this chapter.

(22) Data and information regarding an electronic product submitted as part of the procedures for granting, amending, or extending an exemption from any electronic product performance standard, as described in § 1010.5 of this chapter.

(f) "Sponsor" means:

(1) A person who initiates and supports, by provision of financial or other resources, a nonclinical laboratory study;

(2) A person who submits a nonclinical study to the Food and Drug Administration in support of an application for a research or marketing permit; or

(3) A testing facility, if it both initiates and actually conducts the study.

(g) "Testing facility" means a person who actually conducts a nonclinical laboratory study, i.e., actually uses the test article in a test system. "Testing facility" includes any establishment required to register under section 510 of the act that conducts nonclinical laboratory studies and any consulting laboratory described in section 704 of the act that conducts such studies. "Testing facility" encompasses only those operational units that are being or have been used to conduct nonclinical laboratory studies.

(h) "Person" includes an individual, partnership, corporation, association, scientific or academic establishment, government agency, or organizational unit thereof, and any other legal entity.

(i) "Test system" means any animal, plant, microorganism, or subparts thereof to which the test or control article is administered or added for study. "Test system" also includes appropriate groups or components of the system not treated with the test or control articles.

(j) "Specimen" means any material derived from a test system for examination or analysis.

(k) "Raw data" means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a nonclinical laboratory study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. "Raw data" may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

(l) "Quality assurance unit" means any person or organizational element, except the study director, designated by testing facility management to perform the duties relating to quality assurance of nonclinical laboratory studies.

(m) "Study director" means the individual responsible for the overall conduct of a nonclinical laboratory study.

(n) "Batch" means a specific quantity or lot of a test or control article that has been characterized according to § 58.105(a).

§ 58.10 Applicability to studies performed under grants and contracts.

When a sponsor conducting a nonclinical laboratory study intended to be submitted to or reviewed by the Food and Drug Administration utilizes the services of a consulting laboratory, contractor, or grantee to perform an analysis or other service, it shall notify the consulting laboratory, contractor, or grantee that the service is part of a nonclinical laboratory study that must be conducted in compliance with the provisions of this part.

§ 58.15 Inspection of a testing facility.

(a) A testing facility shall permit an authorized employee of the Food and Drug Administration, at reasonable times and in a reasonable manner, to inspect the facility and to inspect (and in the case of records also to copy) all records and specimens required to be maintained regarding studies within the scope of this part. The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken.

(b) The Food and Drug Administration will not consider a nonclinical laboratory study in support of an application for a research or marketing permit if the testing facility refuses to permit inspection. The determination that a nonclinical laboratory study will not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any applicable statute or regulation to submit the results of the study to the Food and Drug Administration.

Subpart B—Organization and Personnel

§ 58.29 Personnel.

(a) Each individual engaged in the conduct of or responsible for the supervision of a nonclinical laboratory study shall have education, training, and experience, or combination thereof, to enable that individual to perform the assigned functions.

(b) Each testing facility shall maintain a current summary of training

and experience and job description for each individual engaged in or supervising the conduct of a nonclinical laboratory study.

(c) There shall be a sufficient number of personnel for the timely and proper conduct of the study according to the protocol.

(d) Personnel shall take necessary personal sanitation and health precautions designed to avoid contamination of test and control articles and test systems.

(e) Personnel engaged in a nonclinical laboratory study shall wear clothing appropriate for the duties they perform. Such clothing shall be changed as often as necessary to prevent microbiological, radiological, or chemical contamination of test systems and test and control articles.

(f) Any individual found at any time to have an illness that may adversely affect the quality and integrity of the nonclinical laboratory study shall be excluded from direct contact with test systems, test and control articles and any other operation or function that may adversely affect the study until the condition is corrected. All personnel shall be instructed to report to their immediate supervisors any health or medical conditions that may reasonably be considered to have an adverse effect on a nonclinical laboratory study.

§ 58.31 Testing facility management.

For each nonclinical laboratory study, testing facility management shall:

(a) Designate a study director as described in § 58.33, before the study is initiated.

(b) Replace the study director promptly if it becomes necessary to do so during the conduct of a study, and document and maintain such action as raw data.

(c) Assure that there is a quality assurance unit as described in § 58.35.

(d) Assure that test and control articles or mixtures have been appropriately tested for identity, strength, purity, stability, and uniformity, as applicable.

(e) Assure that personnel, resources, facilities, equipment, materials, and methodologies are available as scheduled.

(f) Assure that personnel clearly understand the functions they are to perform.

(g) Assure that any deviations from these regulations reported by the quality assurance unit are communicated to the study director and corrective actions are taken and documented.

§ 58.33 Study director.

For each nonclinical laboratory study, a scientist or other professional

of appropriate education, training, and experience, or combination thereof, shall be identified as the study director. The study director has overall responsibility for the technical conduct of the study, as well as for the interpretation, analysis, documentation and reporting of results, and represents the single point of study control. The study director shall assure that:

(a) The protocol, including any change, is approved as provided by § 58.120 and is followed.

(b) All experimental data, including observations of unanticipated responses to the test system are accurately recorded and verified.

(c) Unforeseen circumstances that may affect the quality and integrity of the nonclinical laboratory study are noted when they occur, and corrective action is taken and documented.

(d) Test systems are as specified in the protocol.

(e) All applicable good laboratory practice regulations are followed.

(f) All raw data, documentation, protocols, specimens, and final reports are transferred to the archives during or at the close of the study.

§ 58.35 Quality assurance unit.

(a) A testing facility shall have a quality assurance unit composed of one or more individuals who shall be responsible for monitoring each study to assure management that the facilities, equipment, personnel, methods, practices, records, and controls are in conformance with the regulations in this part. For any given study the quality assurance unit shall be entirely separate from and independent of the personnel engaged in the direction and conduct of that study.

(b) The quality assurance unit shall:

(1) Maintain a copy of a master schedule sheet of all nonclinical laboratory studies conducted at the testing facility indexed by test article and containing the test system, nature of study, date study was initiated, current status of each study, name of the sponsor, name of the study director, and status of the final report.

(2) Maintain copies of all protocols pertaining to all nonclinical laboratory studies for which the unit is responsible.

(3) Inspect each phase of a nonclinical laboratory study periodically and maintain written and properly signed records of each periodic inspection showing the date of the inspection, the study inspected, the phase or segment of the study inspected, the person performing the inspection, findings and problems, action recommended and taken to resolve existing problems, and any scheduled date for re-inspection. For studies lasting more than 6 months, inspections shall be conducted every 3 months. For studies

lasting less than 6 months, inspections shall be conducted at intervals adequate to assure the integrity of the study. Any significant problems which are likely to affect study integrity found during the course of an inspection shall be brought to the attention of the study director and management immediately.

(4) Periodically submit to management and the study director written status reports on each study, noting any problems and the corrective actions taken.

(5) Determine that no deviations from approved protocols or standard operating procedures were made without proper authorization and documentation.

(6) Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the nonclinical laboratory study.

(7) Prepare and sign a statement to be included with the final study report which shall specify the dates inspections were made and findings reported to management and to the study director.

(c) The responsibilities and procedures applicable to the quality assurance unit, the records maintained by the quality assurance unit, and the method of indexing such records shall be in writing and shall be maintained. These items including inspection dates, the study inspected, the phase or segment of the study inspected, and the name of the individual performing the inspection shall be made available for inspection to authorized employees of the Food and Drug Administration.

(d) A designated representative of the Food and Drug Administration shall have access to the written procedures established for the inspection and may request testing facility management to certify that inspections are being implemented, performed, documented, and followed-up in accordance with this paragraph.

(e) All records maintained by the quality assurance unit shall be kept in one location at the testing facility.

Subpart C—Facilities

§ 58.41 General.

Each testing facility shall be of suitable size, construction, and location to facilitate the proper conduct of nonclinical laboratory studies. It shall be designed so that there is a degree of separation that will prevent any function or activity from having an adverse effect on the study.

§ 58.43 Animal care facilities.

(a) A testing facility shall have a sufficient number of animal rooms or areas, as needed, to assure proper: (1)

Separation of species or test systems, (2) isolation of individual projects, (3) quarantine of animals, and (4) routine or specialized housing of animals.

(b) A testing facility shall have a number of animal rooms or areas separate from those described in paragraph (a) of this section to ensure isolation of studies being done with test systems or test and control articles known to be biohazardous, including volatile substances, aerosols, radioactive materials, and infectious agents.

(c) Separate areas shall be provided for the diagnosis, treatment, and control of laboratory animal diseases. These areas shall provide effective isolation for the housing of animals either known or suspected of being diseased, or of being carriers of disease, from other animals.

(d) When animals are housed, facilities shall exist for the collection and disposal of all animal waste and refuse or for safe sanitary storage of waste before removal from the testing facility. Disposal facilities shall be so provided and operated as to minimize vermin infestation, odors, disease hazards, and environmental contamination.

(e) Animal facilities shall be designed, constructed, and located so as to minimize disturbances that interfere with the study.

§ 58.45 Animal supply facilities.

There shall be storage areas, as needed, for feed, bedding, supplies, and equipment. Storage areas for feed and bedding shall be separated from areas housing the test systems and shall be protected against infestation or contamination. Refrigeration shall be provided for perishable supplies or feed.

§ 58.47 Facilities for handling test and control articles.

(a) As necessary to prevent contamination or mixups, there shall be separate areas for:

(1) Receipt and storage of the test and control articles.

(2) Mixing of the test and control articles with a carrier, e.g., feed.

(3) Storage of the test and control article mixtures.

(b) Storage areas for the test and/or control article and test and control mixtures shall be separate from areas housing the test systems and shall be adequate to preserve the identity, strength, purity, and stability of the articles and mixtures.

§ 58.49 Laboratory operation areas.

(a) Separate laboratory space shall be provided, as needed, for the performance of the routine procedures required by nonclinical laboratory studies, including specialized areas for performing activities such as aseptic sur-

gery, intensive care, necropsy, histology, radiography, and handling of biohazardous materials.

(b) Separate space shall be provided for cleaning, sterilizing, and maintaining equipment and supplies used during the course of the study.

§ 58.51 Specimen and data storage facilities.

Space shall be provided for archives, limited to access by authorized personnel only, for the storage and retrieval of all raw data and specimens from completed studies.

§ 58.53 Administrative and personnel facilities.

(a) There shall be space provided for the administration, supervision, and direction of the testing facility.

(b) Separate space shall be provided for locker, shower, toilet, and washing facilities, as needed.

Subpart D—Equipment

§ 58.61 Equipment design.

Automatic, mechanical, or electronic equipment used in the generation, measurement, or assessment of data and equipment used for facility environmental control shall be of appropriate design and adequate capacity to function according to the protocol and shall be suitably located for operation, inspection, cleaning, and maintenance.

§ 58.63 Maintenance and calibration of equipment.

(a) Equipment shall be adequately inspected, cleaned, and maintained. Equipment used for the generation, measurement, or assessment of data shall be adequately tested, calibrated and/or standardized.

(b) The written standard operating procedures required under § 58.81(b)(11) shall set forth in sufficient detail the methods, materials, and schedules to be used in the routine inspection, cleaning, maintenance, testing, calibration and/or standardization of equipment, and shall specify remedial action to be taken in the event of failure or malfunction of equipment. The written standard operating procedures shall designate the person responsible for the performance of each operation, and copies of the standard operating procedures shall be made available to laboratory personnel.

(c) Written records shall be maintained of all inspection, maintenance, testing, calibrating and/or standardizing operations. These records, containing the date of the operation, shall describe whether the maintenance operations were routine and followed the written standard operating procedures. Written records shall be kept of nonroutine repairs performed on

equipment as a result of failure and malfunction. Such records shall document the nature of the defect, how and when the defect was discovered, and any remedial action taken in response to the defect.

Subpart E—Testing Facilities Operation

§ 58.81 Standard operating procedures.

(a) A testing facility shall have standard operating procedures in writing setting forth nonclinical laboratory study methods that management is satisfied are adequate to insure the quality and integrity of the data generated in the course of a study. All deviations in a study from standard operating procedures shall be authorized by the study director and shall be documented in the raw data. Significant changes in established standard operating procedures shall be properly authorized in writing by management.

(b) Standard operating procedures shall be established for, but not limited to, the following:

- (1) Animal room preparation.
- (2) Animal care.
- (3) Receipt, identification, storage, handling, mixing, and method of sampling of the test and control articles.
- (4) Test system observations.
- (5) Laboratory tests.
- (6) Handling of animals found moribund or dead during study.
- (7) Necropsy of animals or postmortem examination of animals.
- (8) Collection and identification of specimens.
- (9) Histopathology.
- (10) Data handling, storage, and retrieval.
- (11) Maintenance and calibration of equipment.
- (12) Transfer, proper placement, and identification of animals.

(c) Each laboratory area shall have immediately available laboratory manuals and standard operating procedures relative to the laboratory procedures being performed, e.g., toxicology, histology, clinical chemistry, hematology, teratology, necropsy. Published literature may be used as a supplement to standard operating procedures.

(d) A historical file of standard operating procedures, and all revisions thereof, including the dates of such revisions, shall be maintained.

§ 58.83 Reagents and solutions.

All reagents and solutions in the laboratory areas shall be labeled to indicate identity, titer or concentration, storage requirements, and expiration date. Deteriorated or outdated reagents and solutions shall not be used.

§ 58.90 Animal care.

(a) There shall be standard operating procedures for the housing, feeding, handling, and care of animals.

(b) All newly received animals from outside sources shall be placed in quarantine until their health status has been evaluated. This evaluation shall be in accordance with acceptable veterinary medical practice.

(c) At the initiation of a nonclinical laboratory study, animals shall be free of any disease or condition that might interfere with the purpose or conduct of the study. If, during the course of the study, the animals contract such a disease or condition, the diseased animals shall be isolated. If necessary, these animals may be treated for disease or signs of disease provided that such treatment does not interfere with the study. The diagnosis, authorizations of treatment, description of treatment and each date of treatment shall be documented and shall be retained.

(d) Warm-blooded animals, excluding suckling rodents, used in laboratory procedures that require manipulations and observations over an extended period of time or in studies that require the animals to be removed from and returned to their home cages for any reason (e.g., cage cleaning, treatment, etc.), shall receive appropriate identification (e.g., tattoo, toe clip, color code, ear tag, ear punch, etc.). All information needed to specifically identify each animal within an animal-housing unit shall appear on the outside of that unit.

(e) Animals of different species shall be housed in separate rooms when necessary. Animals of the same species, but used in different studies, should not ordinarily be housed in the same room when inadvertent exposure to control or test articles or animal mixup could affect the outcome of either study. If such mixed housing is necessary, adequate differentiation by space and identification shall be made.

(f) Animal cages, racks and accessory equipment shall be cleaned and sanitized at appropriate intervals.

(g) Feed and water used for the animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed or water are not present at levels above those specified in the protocol. Documentation of such analyses shall be maintained as raw data.

(h) Bedding used in animal cages or pens shall not interfere with the purpose or conduct of the study and shall be changed as often as necessary to keep the animals dry and clean.

(i) If any pest control materials are used, the use shall be documented. Cleaning and pest control materials

that interfere with the study shall not be used.

Subpart F—Test and Control Articles

§ 58.105 Test and control article characterization.

(a) The identity, strength, purity, and composition or other characteristics which will appropriately define the test or control article shall be determined for each batch and shall be documented before the initiation of the study. Methods of synthesis, fabrication, or derivation of the test and control articles shall be documented by the sponsor or the testing facility. In those cases where marketed products are used as control articles, such products will be characterized by their labeling.

(b) The stability of each test or control article shall be determined by the testing facility or by the sponsor before initiation or a nonclinical laboratory study. If the stability of the test and control articles cannot be determined before initiation of a study, standard operating procedures shall be established and followed to provide for periodic re-analysis of each batch.

(c) Each storage container for a test or control article shall be labeled by name, chemical abstract number or code number, batch number, expiration date, if any, and, where appropriate, storage conditions necessary to maintain the identity, strength, purity, and composition of the test or control article. Storage containers shall be assigned to a particular test article for the duration of the study.

(d) For studies of more than 4 weeks' duration, reserve samples from each batch of test and control articles shall be retained for the period of time provided by § 58.195.

§ 58.107 Test and control article handling.

Procedures shall be established for a system for the handling of the test and control articles to ensure that:

- (a) There is proper storage.
- (b) Distribution is made in a manner designed to preclude the possibility of contamination, deterioration, or damage.
- (c) Proper identification is maintained throughout the distribution process.

(d) The receipt and distribution of each batch is documented. Such documentation shall include the date and quantity of each batch distributed or returned.

§ 58.113 Mixtures of articles with carriers.

(a) For each test or control article that is mixed with a carrier, tests by appropriate analytical methods shall be conducted:

- (1) To determine the uniformity of the mixture and to determine, periodi-

cally, the concentration of the test or control article in the mixture.

(2) To determine the stability of the test and control articles in the mixture. If the stability cannot be determined before initiation of the study, standard operating procedures shall be established and followed to provide for periodic re-analysis of the test and control articles in the mixture.

(b) For studies of more than 4 weeks' duration a reserve sample of each test or control carrier article mixture shall be taken and retained for the period of time provided by § 58.195.

(c) Where any of the components of the test or control article carrier mixture has an expiration date, that date shall be clearly shown on the container. If more than one component has an expiration date, the earliest date shall be shown.

Subpart G—Protocol for and Conduct of a Nonclinical Laboratory Study

§ 58.120 Protocol.

(a) Each study shall have an approved written protocol that clearly indicates the objectives and all methods for the conduct of the study. The protocol shall contain but shall not necessarily be limited to the following information:

(1) A descriptive title and statement of the purpose of the study.

(2) Identification of the test and control articles by name, chemical abstract number or code number.

(3) The name of the sponsor and the name and address of the testing facility at which the study is being conducted.

(4) The proposed starting and completion dates.

(5) Justification for selection of the test system.

(6) Where applicable, the number, body weight range, sex, source of supply, species, strain, substrain, and age of the test system.

(7) The procedure for identification of the test system.

(8) A description of the experimental design, including the methods for the control of bias.

(9) A description and/or identification of the diet used in the study as well as solvents, emulsifiers and/or other materials used to solubilize or suspend the test or control articles before mixing with the carrier. The description shall include specifications for acceptable levels of contaminants that are reasonably expected to be present in the dietary materials and are known to be capable of interfering with the purpose or conduct of the study if present at levels greater than established by the specifications.

(10) The route of administration and the reason for its choice.

(11) Each dosage level, expressed in milligrams per kilogram of body weight or other appropriate units, of the test or control article to be administered and the method and frequency of administration.

(12) Method by which the degree of absorption of the test and control articles by the test system will be determined if necessary to achieve the objectives of the study.

(13) The type and frequency of tests, analyses, and measurements to be made.

(14) The records to be maintained.

(15) The date of approval of the protocol by the sponsor and the signature of the study director.

(16) A statement of the proposed statistical methods to be used.

(b) All changes in or revisions of an approved protocol and the reasons therefor shall be documented, signed by the study director, dated, and maintained with the protocol.

§ 58.130 Conduct of a nonclinical laboratory study.

(a) The nonclinical laboratory study shall be conducted in accordance with the protocol.

(b) The test systems shall be monitored in conformity with the protocol.

(c) Specimens shall be identified by test system, study, nature, and date of collection. This information shall be located on the specimen container or shall accompany the specimen in a manner that precludes error in the recording and storage of data.

(d) Records of gross findings for a specimen from postmortem observations shall be available to a pathologist when examining that specimen histopathologically.

(e) All data generated during the conduct of a nonclinical laboratory study, except those that are generated as direct computer input, shall be recorded directly, promptly, and legibly in ink. All data entries shall be dated on the day of entry and signed or initialed by the person entering the data. Any change in entries shall be made so as not to obscure the original entry, shall indicate the reason for such change, and shall be dated and signed or identified at the time of the change. In computer driven data collection systems, the individual responsible for direct data input shall be identified at the time of data input. Any change in computer entries shall be made so as not to obscure the original entry, shall indicate the reason for change, and shall be dated and the responsible individual shall be identified.

Subparts H-I—[Reserved]

Subpart J—Records and Reports

§ 58.185 Reporting of nonclinical laboratory study results.

(a) A final report shall be prepared for each nonclinical laboratory study and shall include, but not necessarily be limited to, the following:

(1) Name and address of the facility performing the study and the dates on which the study was initiated and completed.

(2) Objectives and procedures stated in the approved protocol, including any changes in the original protocol.

(3) Statistical methods employed for analyzing the data.

(4) The test and control articles identified by name, chemical abstracts number or code number, strength, purity, and composition or other appropriate characteristics.

(5) Stability of the test and control articles under the conditions of administration.

(6) A description of the methods used.

(7) A description of the test system used. Where applicable, the final report shall include the number of animals used, sex, body weight range, source of supply, species, strain and substrain, age, and procedure used for identification.

(8) A description of the dosage, dosage regimen, route of administration, and duration.

(9) A description of all circumstances that may have affected the quality or integrity of the data.

(10) The name of the study director, the names of other scientists or professionals, and the names of all supervisory personnel, involved in the study.

(11) A description of the transformations, calculations, or operations performed on the data, a summary and analysis of the data, and a statement of the conclusions drawn from the analysis.

(12) The signed and dated reports of each of the individual scientists or other professionals involved in the study.

(13) The locations where all specimens, raw data, and the final report are to be stored.

(14) The statement prepared and signed by the quality assurance unit as described in § 58.35(b)(7).

(b) The final report shall be signed by the study director.

(c) Corrections or additions to a final report shall be in the form of an amendment by the study director. The amendment shall clearly identify that part of the final report that is being added to or corrected and the reasons for the correction or addition, and

shall be signed and dated by the person responsible.

§ 58.190 Storage and retrieval of records and data.

(a) All raw data, documentation, protocols, specimens, and final reports generated as a result of a nonclinical laboratory study shall be retained.

(b) There shall be archives for orderly storage and expedient retrieval of all raw data, documentation, protocols, specimens, and interim and final reports. Conditions of storage shall minimize deterioration of the documents or specimens in accordance with the requirements for the time period of their retention and the nature of the documents or specimens. A testing facility may contract with commercial archives to provide a repository for all material to be retained. Raw data and specimens may be retained elsewhere provided that the archives have specific reference to those other locations.

(c) An individual shall be identified as responsible for the archives.

(d) Only authorized personnel shall enter the archives.

(e) Material retained or referred to in the archives shall be indexed by test article, date of study, test system, and nature of study.

§ 58.195 Retention of records.

(a) Record retention requirements set forth in this section do not supersede the record retention requirements of any other regulations in this chapter.

(b) Except as provided in paragraph (c) of this section, documentation records, raw data and specimens pertaining to a nonclinical laboratory study and required to be made by this part shall be retained in the archive(s) for whichever of the following periods is shortest:

(1) A period of at least 2 years following the date on which an application for a research or marketing permit, in support of which the results of the nonclinical laboratory study were submitted, is approved by the Food and Drug Administration. This requirement does not apply to studies supporting notices of claimed investigational exemption for new drugs (IND's) or applications for investigational device exemptions (IDE's), records of which shall be governed by the provisions of paragraph (b)(2) of this section.

(2) A period of at least 5 years following the date on which the results of the nonclinical laboratory study are submitted to the Food and Drug Administration in support of an application for a research or marketing permit.

(3) In other situations (e.g., where the nonclinical laboratory study does not result in the submission of the

study in support of an application for a research or marketing permit), a period of at least 2 years following the date on which the study is completed, terminated, or discontinued.

(c) Wet specimens, samples of test or control articles, samples of test or control article carrier mixtures and specially prepared material (e.g., histochemical, electron microscopic, blood mounts, teratological preparation, and uteri from dominant lethal mutagenesis tests), which are relatively fragile and differ markedly in stability and quality during storage, shall be retained only as long as the quality of the preparation affords evaluation. In no case shall retention be required for longer periods than those set forth in paragraphs (a) and (b) of this section.

(d) The master schedule sheet, copies of protocols, and records of quality assurance inspections, as required by § 58.35(c) shall be maintained by the quality assurance unit as an easily accessible system of records for the period of time specified in paragraphs (a) and (b) of this section.

(e) Summaries of training and experience and job descriptions required to be maintained by § 58.29(b) may be retained along with all other testing facility employment records for the length of time specified in paragraphs (a) and (b) of this section.

(f) Records and reports of the maintenance and calibration and inspection of equipment, as required by § 58.63(b) and (c), shall be retained for the length of time specified in paragraph (b) of this section.

(g) If a facility conducting nonclinical testing goes out of business, all raw data, documentation, and other material specified in this section shall be transferred to the archives of the sponsor of the study. The Food and Drug Administration shall be notified in writing of such a transfer.

Subpart K—Disqualification of Testing Facilities

§ 58.200 Purpose.

(a) The purposes of disqualification are: (1) To permit the exclusion from consideration of completed studies that were conducted by a testing facility which has failed to comply with the requirements of the good laboratory practice regulations until it can be adequately demonstrated that such noncompliance did not occur during, or did not affect the validity or acceptability of data generated by, a particular study; and (2) to exclude from consideration all studies completed after the date of disqualification until the facility can satisfy the Commissioner that it will conduct studies in compliance with such regulations.

(b) The determination that a nonclinical laboratory study may not be

considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

§ 58.202 Grounds for disqualification.

The Commissioner may disqualify a testing facility upon finding all of the following:

(a) The testing facility failed to comply with one or more of the regulations set forth in this part (or any other regulations regarding such facilities in this chapter);

(b) The noncompliance adversely affected the validity of the nonclinical laboratory studies; and

(c) Other lesser regulatory actions (e.g., warnings or rejection of individual studies) have not been or will probably not be adequate to achieve compliance with the good laboratory practice regulations.

§ 58.204 Notice of and opportunity for hearing on proposed disqualification.

(a) Whenever the Commissioner has information indicating that grounds exist under § 58.202 which in his opinion justify disqualification of a testing facility, he may issue to the testing facility a written notice proposing that the facility be disqualified.

(b) A hearing on the disqualification shall be conducted in accordance with the requirements for a regulatory hearing set forth in Part 16 of this chapter.

§ 58.206 Final order on disqualification.

(a) If the Commissioner, after the regulatory hearing, or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, makes the findings required in § 58.202, he shall issue a final order disqualifying the facility. Such order shall include a statement of the basis for that determination. Upon issuing a final order, the Commissioner shall notify (with a copy of the order) the testing facility of the action.

(b) If the Commissioner, after a regulatory hearing or after the time for requesting a hearing expires without a request being made, upon an evaluation of the administrative record of the disqualification proceeding, does not make the findings required in § 58.202, he shall issue a final order terminating the disqualification proceeding. Such order shall include a statement of the basis for that determination. Upon issuing a final order the Commissioner shall notify the testing facility and provide a copy of the order.

§ 58.210 Actions upon disqualification.

(a) Once a testing facility has been disqualified, each application for a research or marketing permit, whether approved or not, containing or relying upon any nonclinical laboratory study conducted by the disqualified testing facility may be examined to determine whether such study was or would be essential to a decision. If it is determined that a study was or would be essential, the Food and Drug Administration shall also determine whether the study is acceptable, notwithstanding the disqualification of the facility. Any study done by a testing facility before or after disqualification may be presumed to be unacceptable, and the person relying on the study may be required to establish that the study was not affected by the circumstances that led to the disqualification, e.g., by submitting validating information. If the study is then determined to be unacceptable, such data such be eliminated from consideration in support of the application; and such elimination may serve as new information justifying the termination or withdrawal of approval of the application.

(b) No nonclinical laboratory study begun by a testing facility after the date of the facility's disqualification shall be considered in support of any application for a research or marketing permit, unless the facility has been reinstated under § 58.219. The determination that a study may not be considered in support of an application for a research or marketing permit does not, however, relieve the applicant for such a permit of any obligation under any other applicable regulation to submit the results of the study to the Food and Drug Administration.

§ 58.213 Public disclosure of information regarding disqualification.

(a) Upon issuance of a final order disqualifying a testing facility under § 58.206(a), the Commissioner may notify all or any interested persons. Such notice may be given at the discretion of the Commissioner whenever he believes that such disclosure would further the public interest or would promote compliance with the good laboratory practice regulations set forth in this part. Such notice, if given, shall include a copy of the final order issued under § 58.206(a) and shall state that the disqualification constitutes a determination by the Food and Drug Administration that nonclinical laboratory studies performed by the facility will not be considered by the Food and Drug Administration in support of any application for a research or marketing permit. If such notice is sent to another Federal Government agency, the Food and Drug Administration will recommend that the agency also consider whether or not it should

accept nonclinical laboratory studies performed by the testing facility. If such notice is sent to any other person, it shall state that it is given because of the relationship between the testing facility and the person being notified and that the Food and Drug Administration is not advising or recommending that any action be taken by the person notified.

(b) A determination that a testing facility has been disqualified and the administrative record regarding such determination are disclosable to the public under Part 20 of this chapter.

§ 58.215 Alternative or additional actions to disqualification.

(a) Disqualification of a testing facility under this subpart is independent of, and neither in lieu of nor a precondition to, other proceedings or actions authorized by the act. The Food and Drug Administration may, at any time, institute against a testing facility and/or against the sponsor of a nonclinical laboratory study that has been submitted to the Food and Drug Administration any appropriate judicial proceedings (civil or criminal) and any other appropriate regulatory action, in addition to or in lieu of, and prior to, simultaneously with, or subsequent to, disqualification. The Food and Drug Administration may also refer the matter to another Federal, State, or local government law enforcement or regulatory agency for such action as that agency deems appropriate.

(b) The Food and Drug Administration may refuse to consider any particular nonclinical laboratory study in support of an application for a research or marketing permit, if it finds that the study was not conducted in accordance with the good laboratory practice regulations set forth in this part, without disqualifying the testing facility that conducted the study or undertaking other regulatory action.

§ 58.217 Suspension or termination of a testing facility by a sponsor.

Termination of a testing facility by a sponsor is independent of, and neither in lieu of nor a precondition to, proceedings or actions authorized by this subpart. If a sponsor terminates or suspends a testing facility from further participation in a nonclinical laboratory study that is being conducted as part of any application for a research or marketing permit that has been submitted to any Bureau of the Food and Drug Administration (whether approved or not), it shall notify that Bureau in writing within 15 working days of the action; the notice shall include a statement of the reasons for such action. Suspension or termination of a testing facility by a sponsor does not relieve it of any obligation under any other applicable reg-

ulation to submit the results of the study to the Food and Drug Administration.

§ 58.219 Reinstatement of a disqualified testing facility.

A testing facility that has been disqualified may be reinstated as an acceptable source of nonclinical laboratory studies to be submitted to the Food and Drug Administration if the Commissioner determines, upon an evaluation of the submission of the testing facility, that the facility can adequately assure that it will conduct future nonclinical laboratory studies in compliance with the good laboratory practice regulations set forth in this part and, if any studies are currently being conducted, that the quality and integrity of such studies have not been seriously compromised. A disqualified testing facility that wishes to be so reinstated shall present in writing to the Commissioner reasons why it believes it should be reinstated and a detailed description of the corrective actions it has taken or intends to take to assure that the acts or omissions which led to its disqualification will not recur. The Commissioner may condition reinstatement upon the testing facility being found in compliance with the good laboratory practice regulations upon an inspection. If a testing facility is reinstated, the Commissioner shall so notify the testing facility and all organizations and persons who were notified, under § 58.213 of the disqualification of the testing facility. A determination that a testing facility has been reinstated is disclosable to the public under Part 20 of this chapter.

PART 71—COLOR ADDITIVE PETITIONS

3. Part 71 is amended:

a. § 71.1 by adding new paragraph (g), to read as follows:

§ 71.1 Petitions.

(g) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 706(b) of the act shall include with respect to each nonclinical study contained in the petition, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

b. In § 71.6(b) by adding a new sentence at the end of the paragraph to read as follows:

§ 71.6 Extension of time for studying petitions; substantive amendments; withdrawal of petitions without prejudice.

(b) * * *. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical laboratory study contained in the petition, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

Subchapter B—Food for Human Consumption
PART 170—FOOD ADDITIVES

4. Part 170 is amended:

a. In § 170.17 by adding new paragraph (c), to read as follows:

§ 170.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in Part 58 of this chapter.

b. In § 170.35 by adding new paragraph (c)(1)(vi) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

(c) * * *

(1) * * *

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in

the study and those required in the regulations.

PART 171—FOOD ADDITIVE PETITIONS

5. Part 171 is amended:

a. In § 171.1 by adding new paragraph (k) to read as follows:

§ 171.1 Petitions.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each nonclinical study contained in the petition, either a statement that the study has been, or will be, conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in conducting the study and the good laboratory practice regulations.

b. By revising § 171.6 to read as follows:

§ 171.6 Amendment of petition.

After a petition has been filed, the petitioner may submit additional information or data in support thereof. In such cases, if the Commissioner determines that the additional information or data amount to a substantive amendment, the petition as amended will be given a new filing date, and the time limitation will begin to run anew. Where the substantive amendment proposes a substantial change to any petition that may affect the quality of the human environment, the petitioner is required to submit an environmental analysis report pursuant to § 25.1 of this chapter. If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD ON AN INTERIM BASIS OR IN CONTACT WITH FOOD PENDING ADDITIONAL STUDY

6. Part 180 is amended in § 180.1 by adding new paragraph (c)(4) to read as follows:

§ 180.1 General.

(c) * * *

(4) If nonclinical laboratory studies are involved, studies filed with the Commissioner shall include, with respect to each study, either a statement that the study has been or will be conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in conducting the study and the good laboratory practice regulations.

SUBCHAPTER D—DRUGS FOR HUMAN USE
PART 312—NEW DRUGS FOR INVESTIGATIONAL USE

7. In § 312.1 by adding new item 16 to Form FD-1571 in paragraph (a)(2) and by redesignating paragraph (d)(11) as (d)(12) and adding a new paragraph (d)(11), to read as follows:

§ 312.1 Conditions for exemption of new drugs for investigational use.

(a) * * *

(2) * * *

Form FD-1571 * * *

16. A statement that all nonclinical laboratory studies have been, or will be, conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if such studies have not been conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in conducting the study and those required in the regulations.

(d) * * *

(11) All nonclinical laboratory studies were not conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if such studies were not conducted in compliance with such regulations, all differences between the practices used in conducting the study and the good laboratory practice

regulations were not described in detail; or

PART 314—NEW DRUG APPLICATIONS

8. Part 314 is amended:

a. In § 314.1 by adding new item 16 to Form FD-365H in paragraph (c)(2), by redesignating paragraph (f)(7) as (f)(8) and by adding a new paragraph (f)(7) to read as follows:

§ 314.1 Applications.

(c) ***

(2) ***

Form FD-356H-Rev. 1974 ***

16. *Nonclinical laboratory studies.* With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

(f) ***

(7) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

b. In § 314.8 by adding new paragraph (l) to read as follows:

§ 314.8 Supplemental applications.

(l) A supplemental application that contains nonclinical laboratory studies shall include, with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

c. In § 314.9 by adding paragraph (c) to read as follows:

§ 314.9 Insufficient information in application.

(c) The information contained in an application shall be considered insufficient to determine whether a drug is safe and effective for use unless the application includes, with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

d. In § 314.12 by adding new paragraph (c) to read as follows:

§ 314.12 Untrue statements in application.

(c) All nonclinical laboratory studies contained in the application were not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if such studies were not conducted in compliance with such regulations, differences between the practices used in conducting the study and the good laboratory practice regulations were not described in detail.

e. In § 314.110 by adding new paragraph (a)(9) to read as follows:

§ 314.110 Reasons for refusing to file applications.

(a) ***

(9) The applicant fails to include in the application, with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

f. In § 314.111 by striking the period at the end of paragraph (a)(8), adding in lieu thereof a semicolon and the word "or" and adding new paragraph (a)(9) to read as follows:

§ 314.111 Refusal to approve the application.

(a) ***

(9) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as

set forth in Part 58 of this chapter, or, if such study was not conducted in compliance with such regulations, differences between the practices used in conducting the study and the good laboratory practice regulations were not described in detail.

g. In § 314.115 by adding new paragraph (c)(6) to read as follows:

§ 314.115 Withdrawal of approval of an application.

(c) ***

(6) That any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or any differences between the practices used in conducting the study and those required in the regulations were not described in detail.

PART 330—OVER-THE-COUNTER (OTC) HUMAN DRUGS WHICH ARE GENERALLY RECOGNIZED AS SAFE AND NOT MISBRANDED

9. Part 330 is amended in § 330.10 by adding new paragraph (c) to read as follows:

§ 330.10 Procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded, and for establishing monographs.

(c) Information and data submitted under this section shall include, with respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 430—ANTIBIOTIC DRUGS; GENERAL

10. In § 430.20 by adding new paragraph (e) to read as follows:

§ 430.20 Procedure for the issuance, amendment, or repeal of regulations.

(e) No regulation providing for the certification of an antibiotic drug for human use shall be issued or amended

unless each nonclinical laboratory study on which the issuance or amendment of the regulation is based was conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or, if any such study has not been conducted in compliance with such regulations, differences between the practices used in conducting the study and the good laboratory practice regulations shall be described in detail.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

11. In § 431.17 by adding new paragraph (j) to read as follows:

§ 431.17 New antibiotic and antibiotic-containing products.

(j) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

Subchapter E—Animal Drugs, Feeds, and Related Products

PART 511—NEW ANIMAL DRUGS FOR INVESTIGATIONAL USE

12. Part 511 is amended in § 511.1 by revising paragraph (b)(4)(ii), to read as follows:

§ 511.1 New animal drugs for investigational use exempt from section 512(a) of the act.

(b) * * *

(4) * * *

(ii) All labeling and other pertinent information to be supplied to the investigators. When such pertinent information includes nonclinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 514—NEW ANIMAL DRUG APPLICATIONS

13. Part 514 is amended:

a. In § 514.1 by adding new paragraph (b)(12)(iii) to read as follows:

§ 514.1 Applications.

* * *

(b) * * *

(12) * * *

(iii) With respect to each nonclinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

* * *

b. In § 514.8 by adding new paragraph (l) to read as follows:

§ 514.8 Supplemental new animal drug applications.

* * *

(l) A supplemental application that contains nonclinical laboratory studies shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

c. In § 514.15 by adding new paragraph (c) to read as follows:

§ 514.15 Untrue statements in applications.

* * *

(c) Any nonclinical laboratory study contained in the application was conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, and differences between the practices used in the conduct of the study and those required in the regulations were not described in detail.

d. In § 514.110 by adding new paragraph (b)(8) to read as follows:

§ 514.110 Reasons for refusing to file applications.

* * *

(b) * * *

(8) It fails to include, with respect to each nonclinical study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

* * *

e. In § 514.111 by adding new paragraph (a)(11) to read as follows:

§ 514.111 Refusal to approve an application.

(a) * * *

(11) Any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, or any differences between the practices used in conducting the study and those required in the regulations were not described in detail.

* * *

f. In § 514.115 by adding new paragraph (b)(4) to read as follows:

§ 514.115 Withdrawal of approval of applications.

* * *

(b) * * *

(4) That any nonclinical laboratory study contained in the application was not conducted in compliance with the good laboratory practice regulations as set forth in Part 58 of this chapter, and differences between the practices used in conducting the study and the regulations were not described in detail.

* * *

PART 570—FOOD ADDITIVES

14. Part 570 is amended:

a. In § 570.17 by adding new paragraph (c) to read as follows:

§ 570.17 Exemption for investigational use and procedure for obtaining authorization to market edible products from experimental animals.

* * *

(c) If intended for nonclinical laboratory studies in food-producing animals, the study is conducted in compliance with the regulations set forth in Part 58 of this chapter.

b. In § 570.35 by adding new paragraph (c)(1)(vi) to read as follows:

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

(c) ***

(1) ***

(vi) If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each nonclinical study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 571—FOOD ADDITIVE PETITIONS

15. Part 571 is amended:

a. In § 571.1 by adding paragraph (k) to read as follows:

§ 571.1 Petitions.

(k) If nonclinical laboratory studies are involved, petitions filed with the Commissioner under section 409(b) of the act shall include, with respect to each study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

b. In § 571.6 by adding the following sentence to the end of the section to read as follows:

§ 571.6 Amendment of petition.

*** If nonclinical laboratory studies are involved, additional information and data submitted in support of filed petitions shall include, with respect to each such study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

SUBCHAPTER F—BIOLOGICS

PART 601—LICENSING

16. Part 601 is amended:

a. In § 601.2 by revising paragraph (a) to read as follows:

§ 601.2 Applications for establishment and product licenses; procedures for filing.

(a) *General.* To obtain a license for any establishment or product, the manufacturer shall make application to the Director, Bureau of Biologics, on forms prescribed for such purposes, and in the case of an application for a product license, shall submit data derived from nonclinical laboratory and clinical studies which demonstrate that the manufactured product meets prescribed standards of safety, purity, and potency; with respect to each nonclinical laboratory study, either a statement that the study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations; a full description of manufacturing methods; data establishing stability of the product through the dating period; sample(s) representative of the product to be sold, bartered, or exchanged or offered, sent, carried or brought for sale, barter, or exchange; summaries of results of tests performed on the lot(s) represented by the submitted sample(s); and specimens of the labels, enclosures and containers proposed to be used for the product. An application for license shall not be considered as filed until all pertinent information and data shall have been received from the manufacturer by the Bureau of Biologics. In lieu of the procedures described in this paragraph, applications for radioactive biological products shall be handled as set forth in paragraph (b) of this section.

b. By revising § 601.30 to read as follows:

§ 601.30 Licenses required; products for controlled investigation only.

Any biological or trivalent organic arsenical manufactured in any foreign country and intended for sale, barter or exchange shall be refused entry by collectors of customs unless manufactured in an establishment holding an unsuspended and unrevoked establishment license and license for the product. Unlicensed products that are not imported for sale, barter or exchange and that are intended solely for purposes of controlled investigation are admissible only if the investigation is conducted in accordance with section 505 of the Federal Food, Drug, and Cosmetic Act and the requirements set

forth in Parts 58 and 312 of this chapter.

SUBCHAPTER J—RADIOLOGICAL HEALTH

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

17. Part 1003 is amended in § 1003.31 by revising paragraph (b), to read as follows:

§ 1003.31 Granting the exemption.

(b) Such views and evidence shall be confined to matters relevant to whether the defect in the product or its failure to comply with an applicable Federal standard is such as to create a significant risk of injury, including genetic injury, to any person and shall be presented in writing unless the Secretary determines that an oral presentation is desirable. Where such evidence includes nonclinical laboratory studies, the data submitted shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

18. Part 1010 is amended:

a. In § 1010.4 by adding new paragraph (b)(1)(ix) to read as follows:

§ 1010.4 Variances.

(b) ***

(1) ***

(ix) With respect to each nonclinical study contained in the application, either a statement that the study was conducted in compliance with the good laboratory practice regulations set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

b. In § 1010.5 by revising paragraph (c)(12) to read as follows:

§ 1010.5 Exemptions for products intended
for United States Government use.

* * * *

(c) * * *

(12) Such other information required by regulation or by the Director, Bureau of Radiological Health, to evaluate and act on the application. Where such information includes non-clinical laboratory studies, the information shall include, with respect to each nonclinical study, either a statement that each study was conducted in compliance with the requirements set forth in Part 58 of this chapter, or, if the study was not conducted in compliance with such regulations, a statement that describes in detail all differences between the practices used in the study and those required in the regulations.

* * * *

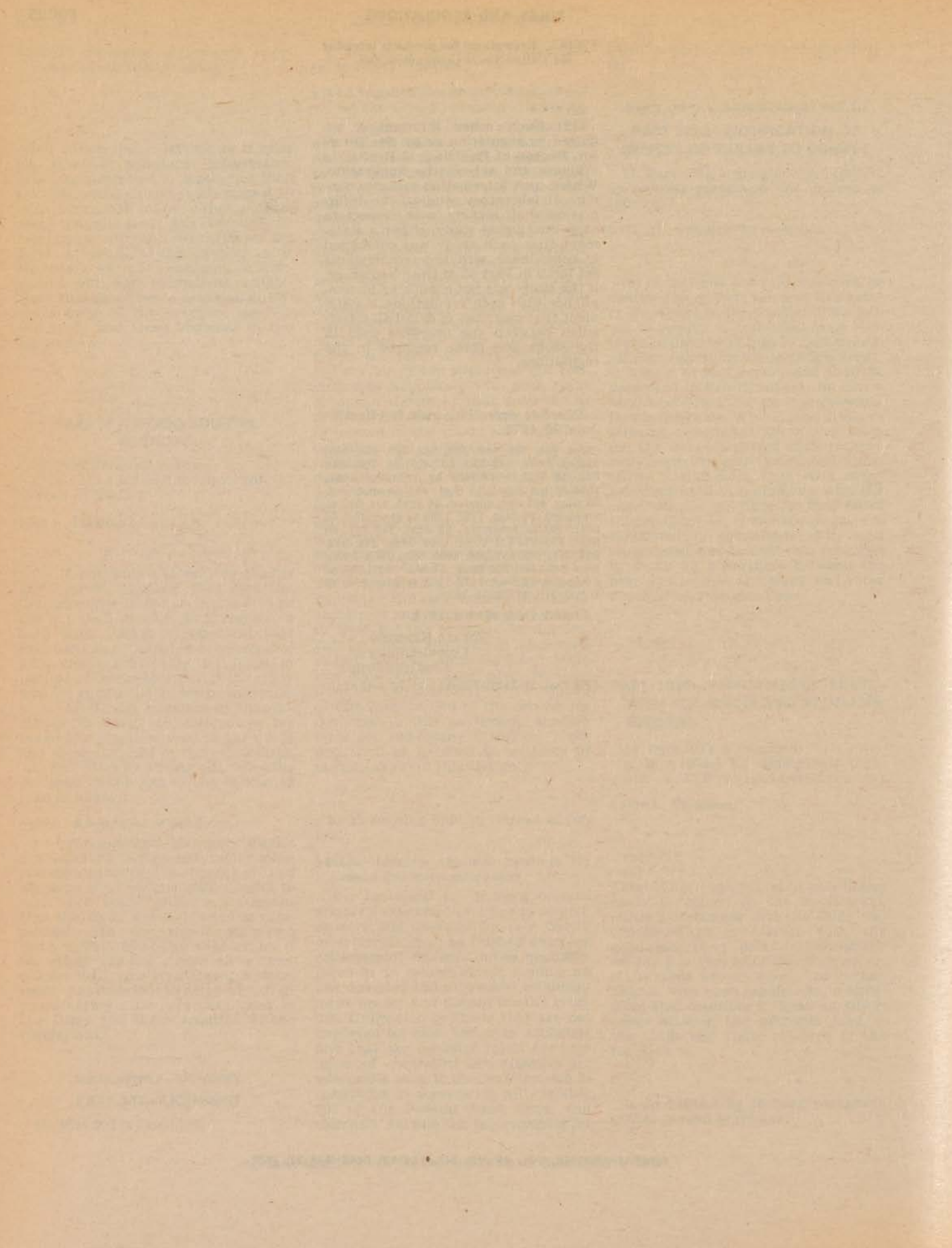
Effective date. This rule is effective June 20, 1979.

(Secs. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512-516, 518-520, 601, 701(a), 706, and 801, 52 Stat. 1049-1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511-517 as amended, 72 Stat. 1785-1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343-351, 90 Stat. 539-574 (21 U.S.C. 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b-360f, 360h-360i); secs. 215, 351, 354-360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173-1186 as amended; 42 U.S.C. 216, 262, 263b-263n).

Dated: December 4, 1978.

DONALD KENNEDY,
Commissioner of
Food and Drugs.

[FR Doc. 78-35272 Filed 12-21-78; 8:45 am]



Registered
Property

FRIDAY, DECEMBER 22, 1978
PART III



**DEPARTMENT OF
LABOR**

**Employment Standards
Administration**



**MINIMUM WAGES FOR
FEDERAL AND FEDERALLY
ASSISTED
CONSTRUCTION**

**General Wage Determination
Decisions**

[4510-27-M]

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 procedures 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 its 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 SUPERSEDES DECISIONS TO GENERAL WAGE DETERMINATION DECISIONS

Modifications and Supersedes 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 Supersedes 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 Supersedes 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 rule-making procedures prescribed in 5 U.S.C. 553 has been set forth in the original general wage determination decision.

NEW GENERAL WAGE DETERMINATION DECISIONS

South Carolina.—SC78-1103.

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.

Connecticut:		
CT78-2160; CT78-2161		Dec. 1, 1978.
Florida:		
FL77-1141		Nov. 25, 1977.
Illinois:		
IL78-2125		Oct. 20, 1978.
IL78-2139		Nov. 3, 1978.
IL78-2166		Dec. 8, 1978.
Louisiana:		
LA78-4099		Oct. 6, 1978.
Pennsylvania:		
PA78-3078		Oct. 20, 1978.
Texas:		
TX78-4115		Dec. 1, 1978.
West Virginia:		
WV78-3018		June 9, 1978.

CANCELLATION OF GENERAL WAGE DETERMINATION DECISIONS

General Wage Determination Decision No. FL77-1143, Escambia, Okaloosa, Santa Rosa, and Walton Counties, Florida is cancelled. Agencies with building construction (non-residential) projects pending in this County should utilize the project determination procedure by submitting form SF-308. See Regulations Part 1.5. Contracts for which bids have been opened shall not be affected by this notice, and consistent with 29 CFR 1.7(b)(2), the incorporations of Decision No. FL77-1143 in contract specifications the opening of bids for which is within ten (10) days of this notice need not be affected.

Signed at Washington, D.C., this 15th day of December 1978.

DOROTHY P. COME,
Assistant Administrator,
Wage and Hour Division.

[4510-27-C]

NEW DECISION

STATE: South Carolina
DECISION NO. SC78-1103
Description of Work: Building Construction (does not include single family homes and garden type apartments up to and including 4 stories.

COUNTY: Georgetown
DATE: Date of Publication

MODIFICATIONS P. 1

	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
Air conditioning mechanic	5.00					
Asbestos workers	9.40	.55	.50			
Boilermakers	10.70	1.05	1.10			.02
Bricklayers	6.00					
Carpenters	4.50					
Cement masons	4.50					
Electricians	5.56					
Glaziers	4.88					
Ironworkers:						
Structural, Ornamental, Reinforcing	5.15					
Laborers:						
Painters, brush	3.21					
Plumbers & steamfitters	5.00					
Roofers	9.50	.30	.20			.08
Sheet metal workers	4.25					
Soft floor layers	5.00					
Sprinkler fitters	6.25					
Truck drivers	8.25					
Tile setters	3.21	.75	1.05			.08
Welders - rate for craft.	6.10					
POWER EQUIPMENT OPERATORS:						
Backhoe	4.13					
Cranes, derricks, draglines	5.00					
Front end loader	3.75					
Motor grader	3.88					
Pans - scrapers	3.50					
Roller	3.40					

FOOTNOTES:

- Holidays - Independence Day, Labor Day, Thanksgiving Day, Christmas Day.

DECISION NO. FL77-1141 - Mod. #5 (42 FR 60552 - November 25, 1977) Volusia County (except Cape Kennedy, Kennedy Space Flight Center, Cape Canaveral Air Force Station), Florida	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
Change: Carpenters Piledrivers	\$7.95 8.25	.50 .50	.50 .50			.05 .05
DECISION #CT78-2160 - MOD #1 (43 FR 56362 - December 1, 1978) Fairfield, Litchfield & Windham Counties, Connecticut						
ADD: PAINTERS Fairfield Co.: Darien, Stamford, New Canaan, Norwalk, Weston, Westport & Wilton Spray Painter Fairfield Co.: Bethel, Brookfield, Danbury, New Fairfield, Newton, Redding, Ridgefield, Sandy Hook, & Sherman; Litchfield Co.: New Milford Spray Painter Windham Co.: Williamantic & Windham Brush & Tapers Paperhangers Kiding Steel; Steamcleaning; Sandblasting; Tanks; Towers & Hazardous Work Spray	\$11.80 16.20 10.20 10.70 10.78 13.20	.50 .50 .95 .95 .95 .95	.75 .50 .70 .70 .70 .70			.01
DECISION #CT78-2161 - MOD #1 (43 FR 56370 - December 1, 1978) Hartford, Middlesex, New Haven, New London and Tolland Counties, Connecticut						
CHANGE: PAINTERS: New Haven Co.: Middlebury, Naugatuck, Prospect, Roxbury, Southbury, Thomaston, Washington, Waterbury, Watertown, Wolcott & Woodbury Spray	13.18	.50		.70		

DECISION #1178-2125 - MOD #1 (43 FR 49192 October 20, 1978) Alexander, Franklin, Gallatin, Hamilton, Hardin, Johnson, Jackson, Jefferson, Marion, Massac, Perry, Pope, Palaski, Saline, Union, White & Williams Counties, Illinois	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr.
		H & W	Pensions	Vacation	
CHANGE: SHEET METAL WORKERS	\$11.23	.55	.90	6%	.02
DECISION #1178-2139 - MOD. # 2 43 FR 51573 - November 3, 1978 Bureau, Carroll, Henry, Lee, Jodavies, Ogle, Rock Island Stephenson, Whiteside and Winnebago Counties, Illinois					
Change: Linemen Rock Island, Henry, Remainder of Carroll, Jodavies and Whiteside: Ground men Truck Drivers: W/ Winch W/O Winch & Groundmen over six months Groundmen Less than six months	8.32 8.05 6.12	.45 .45 .45	3% 3% 3%		1/4 of 1% 1/4 of 1% 1/4 of 1%
DECISION #1178-2166 - MOD #1 (43 FR 57767 December 8, 1978) Kankakee County, Illinois					
CHANGE: ELECTRICIANS: Building Residential	12.42 7.86	.88 .88	32+.70 32+.60		.2 of 1% .2 of 1%

	Basic Hourly Rates	Fringe Benefits Payments			Education and/or Appr. Tr.
		H & W	Pensions	Vacation	
DECISION #1A78-4099 - Mod. #6 (43 FR 46449 - October 6, 1978) Statewide Louisiana					
Change: Electricians: Zone 6 - Electricians Cable splicers Zone 7 - Electricians Cable splicers	\$11.55 12.05 12.05 12.55	.75 .75 1.15 1.15	3% 3% 3% 3%		1/2% 1/2% 1% 1%
DECISION #PA78-3078 - Mod. # 2 (43 FR 49205 - October 20, 1978) Allegheny County, Pennsylvania					
Change: Carpenters (3 story walk-up with no elevator) Electricians (Single or two family houses, walk-up garden type apartments)	\$7.75 7.60	7% .40	7% 3%	.25	1% 1/2%
DECISION #TX78-4115 - Mod. #2 (43 FR 56408 - December 1, 1978) Collin, Dallas, Denton, Ellis, Grayson, Hood, Hunt, Johnson, Kaufman, Palo Pinto, Rockwall, Tarrant & Wise Cos., Texas					
Change: Bricklayers & stonemasons: Zone 3	\$10.50	.45	.50		.04

MODIFICATIONS P. 4

DECISION #WV78-3018 - Mod. #4
(43 FR 25278 - June 9, 1978)
State of West Virginia excluding the
Counties of Berkeley, Jefferson, and Morgan

Change:	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
Bricklayers, Stone Masons, Marble Masons, Terrazzo Workers, & Tile Layers:						
Area 2	11.53	.55	.50	a	.03	
Area 7						
Bricklayers & Stone Masons	11.09	.65	.62		.02	
Tile Layers	10.94	.65	.62		.02	
Carpenters & Piledrivers:						
Area 1						
Carpenters	11.40	.40	.20		.04	
Contracts under \$100,000	11.65	.40	.20		.04	
Contracts \$100,000 or more						
Piledrivers	11.90	.40	.20		.04	
Contracts under \$100,000	12.15	.40	.20		.04	
Contracts \$100,000 or more						
Area 8						
Carpenters	11.92	.50	.50		.02	
Piledrivers	12.17	.50	.50		.02	
Cement Masons & Plasterers:						
Area 7						
Cement Masons	12.10					
Electricians:						
Barbour, Doddridge, Harrison, Lewis, Randolph, & Upshur Counties:						
Wiremen	10.05	.50	34+.52	2.02	.03	
Cable Splicers	11.055	.50	34+.52	2.02	.03	
Boone, Braxton, Calhoun, Clay, Nicholas, Fayette (Falls and Kanawha Tps.), Gilmer, Kanawha, Putnam, Raleigh (Clear Fork & Marsh Fork Tps.), Roane, & Westers Counties:						
Wiremen	13.00	.50	34+.27		.04	
Cable Splicers	14.30	.50	34+.27		.04	
Jackson, Pleasants, Ritchie, Tyler, Wirt, & Wood Counties:						
Wiremen	11.10	.50	34+.27	1.27	.04	
Cable Splicers	11.35	.50	34+.27	1.27	.04	
Marion, Monongalia, Taylor, Preston, & Tucker Counties:						
Wiremen	6.05	.50	34+.02	1.52	.02	
Contracts under \$12,000:						
Wiremen	10.45	.50	34+.02	1.52	.02	
Contracts over \$12,000:						
Wiremen	10.60	.50	34+.02	1.52	.02	
Cable Splicers						

MODIFICATIONS P. 5

DECISION #WV78-3018 - Mod. #4

Change:	Basic Hourly Rates	Fringe Benefits Payments				Education and/or Appr. Tr.
		H & W	Pensions	Vacation		
Electricians						
Cabell & Wayne Counties:						
Wiremen	11.82	.50	34+.82	1.02	.04	
Cable Splicers	12.41	.50	34+.82	1.02	.04	
Lincoln County:						
Wiremen	12.02	.50	34+.82	1.02	.04	
Cable Splicers	12.62	.50	34+.82	1.02	.04	
Logan, Mason, & Mingo Counties:						
Wiremen	12.27	.50	34+.82	1.02	.04	
Cable Splicers	12.88	.50	34+.82	1.02	.04	
Hampshire & Mineral Counties:						
Wiremen	10.90	.80	34+.60		14	
Grant County:						
Wiremen	11.50	.80	34+.60		14	
Ironworkers - Structural, Ornamental, & Reinforcing:						
Area 1	11.17	.90	1.20		.01	
Line Construction:						
Jackson, Pleasants, Ritchie, Tyler, Wirt & Wood Counties:						
Linemen & Equipment Operators	11.00	.60	34+.27	1.27	4 of 14	
Cable Splicers	12.10	.60	34+.27	1.27	4 of 14	
Groundmen	8.80	.60	34+.27	1.27	4 of 14	
Marion, Monongalia, Preston, Taylor, & Tucker Counties:						
Linemen & Equipment Operators	10.45	.50	34+.02	1.52	4 of 14	
Cable Splicers	11.495	.50	34+.02	1.52	4 of 14	
Groundmen & Truck Drivers	8.36	.50	34+.02	1.52	4 of 14	
Barbour, Doddridge, Harrison, Lewis, Randolph, and Upshur Counties:						
Linemen & Equipment Operators	10.05	.50	34+.52	2.02	4 of 14	
Cable Splicers	11.055	.50	34+.52	2.02	4 of 14	
Groundmen & Truck Drivers	8.04	.50	34+.52	2.02	4 of 14	
Millwrights:						
Area 3	11.94	.40	.20		.04	
Sheet Metal Workers:						
Area 5	11.43	.55	.55		.04	

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Registered Product

FRIDAY, DECEMBER 22, 1978

PART IV



CONSUMER PRODUCT SAFETY COMMISSION



BICYCLES

Revised Safety Standards

[6355-01-M]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT
SAFETY COMMISSIONPART 1512—REQUIREMENTS FOR
BICYCLES

Revised Safety Standard

AGENCY: Consumer Product Safety Commission.

ACTION: Revised final regulation.

SUMMARY: The Commission has had a final bicycle safety standard in effect since May 11, 1976. On June 1, 1977 a federal court of appeals remanded to the Commission portions of that standard. Since the Commission has decided not to reissue those portions and not to appeal the court's decision, the standard now in effect is different from the one previously published. For purposes of clarity, the Commission is publishing in this document the existing bicycle standard, as revised to comply with the court order.

EFFECTIVE DATE: The revised standard has been in effect since June 1, 1977.

FOR FURTHER INFORMATION CONTACT:

David Thome, Directorate for Compliance and Enforcement, Consumer Product Safety Commission, Washington, D.C. 20207; telephone (301) 492-6400.

SUPPLEMENTARY INFORMATION: On July 16, 1974 the Commission issued a safety standard applicable to bicycles (16 CFR Part 1512, 39 FR 26100). The Commission amended it on November 13, 1975 (40 FR 52815). As amended, the bicycle standard became effective on May 11, 1976 (except for certain provisions which became effective on November 13, 1976).

On June 1, 1977 the U.S. Court of Appeals for the District of Columbia decided two petitions for review of the Commission's bicycle standard, *Forester v. Consumer Product Safety Commission*, 559 F.2d 774 (1977). As part of its decision, the Court remanded to the Commission the following provisions in the standard:

1. The requirements of § 1512.4(e) and (f), as well as the test procedure of § 1512.18(b) and figure 4, relating to protrusions.

2. The requirement of § 1512.4(h) on screw length.

3. The requirement of § 1512.5(b)(7) that material used for brake pads on bicycles equipped with hand brakes not melt or blister when heated.

4. The requirement included in § 1512.6(c) that the inside dimension of handlebars be no less than or greater than specified dimensions.

5. The requirement included in § 1512.7(a) that the tread be an integral part of the pedal.

On June 29, 1978 the Commission considered staff briefing materials on those provisions and decided not to reissue any of them as requirements. However, the Commission has been discussing whether to issue the remanded provisions as guidelines for bicycle manufacturers rather than as part of the mandatory bicycle standard. If the Commission ever does follow this approach, it plans to notify all affected parties in the FEDERAL REGISTER.

For the convenience of anyone interested in the bicycle standard, the Commission is publishing the standard in its current form, below. To avoid extensive renumbering, the Commission has inserted the notation "revoked" where entire provisions have been deleted in response to the Court's action. In addition, the Commission has deleted from the revised standard the sentence in § 1512.6(c) and portion of a sentence in § 1512.7(a) remanded by the Court, and has made some minor editorial changes.

The Commission amends Title 16, Code of Federal Regulations, Chapter II, Part 1512, as follows:

PART 1512—REQUIREMENTS FOR
BICYCLES

Subpart A—Regulations

Sec.

- 1512.1 Scope.
- 1512.2 Definitions.
- 1512.3 Requirements in general.
- 1512.4 Mechanical requirements.
- 1512.5 Requirements for braking system.
- 1512.6 Requirements for steering system.
- 1512.7 Requirements for pedals.
- 1512.8 Requirements for drive chain.
- 1512.9 Requirements for protective guards.
- 1512.10 Requirements for tires.
- 1512.11 Requirements for wheels.
- 1512.12 Requirements for wheel hubs.
- 1512.13 Requirements for front fork.
- 1512.14 Requirements for fork and frame assembly.
- 1512.15 Requirements for seat.
- 1512.16 Requirements for reflectors.
- 1512.17 Other requirements.
- 1512.18 Test and test procedures.
- 1512.19 Instructions and labeling.
- 1512.20 Separability.

Subpart B—Policies and Interpretations

- 1512.50 Affirmative labeling statement.

AUTHORITY: Secs. 2(f)(1)(D), (q)(1)(A), (s), 3(e)(1), 74 Stat. 372, 374, 375, as amended, 80 Stat. 1304-05, 83 Stat. 187-89 (15 U.S.C. 1261, 1262).

EFFECTIVE DATE: At 40 FR 52835, November 13, 1975, the effective date of Part 1512 was established as May 11, 1976, except for §§ 1512.5(c)(3), 1512.9(a), and 1512.18(e) and

(f), which became effective November 13, 1976. On June 1, 1977, a federal court remanded to the Commission certain provisions of Part 1512 (*Forester v. Consumer Product Safety Commission*, 559 F.2d 774 (C.A.D.C. 1977)). The Commission has deleted these provisions from the standard (where an entire provision is involved, the notation "revoked" is used).

Subpart A—Regulations

§ 1512. Scope.

This part sets forth the requirements for a bicycle as defined in § 1512.2(a) (except a bicycle that is a "track bicycle" or a "one-of-a-kind bicycle" as defined in § 1512.2 (d) and (e)) which is not a banned article under § 1500.18(a)(12) of this chapter.

§ 1512.2 Definitions

For the purposes of this part:

(a) "Bicycle" means a two-wheeled vehicle having a rear drive wheel that is solely human-powered.

(b) "Sidewalk bicycle" means a bicycle with a seat height of no more than 635 mm (25.0 in.); the seat height is measured with the seat adjusted to its highest position.

(c) "Seat height" means the dimension from the point on the seat surface intersected by the seat post center line (or the center of the seating area if no seat post exists) and the ground plane, as measured with the wheels aligned and in a plane normal to the ground plane.

(d) "Track bicycle" means a bicycle designed and intended for sale as a competitive machine having tubular tires, single crank-to-wheel ratio, and no free-wheeling feature between the rear wheel and the crank.

(e) "One-of-a-kind bicycle" means a bicycle that is uniquely constructed to the order of an individual consumer other than by assembly of stock or production parts.

(f) "Normal riding position" means that the rider is seated on the bicycle with both feet on the pedals and both hands on the handlebars (and in a position that allows operation of hand-brake levers if so equipped); the seat and handlebars may be adjusted to positions judged by the rider to be comfortable.

§ 1512.3 Requirements in general.

Any bicycle subject to the regulations in this part shall meet the requirements of this part in the condition to which it is offered for sale to consumers; any bicycle offered for sale to consumers in disassembled or partially assembled condition shall meet these requirements after assembly according to the manufacturer's instructions. For the purpose of compliance with this part, where the metric and English units are not equal due to the conversion process the less stringent requirement will prevail.

§ 1512.4 Mechanical requirements.

(a) *Assembly.* Bicycles shall be manufactured such that mechanical skills required of the consumer for assembly shall not exceed those possessed by an adult of normal intelligence and ability.

(b) *Sharp edges.* There shall be no unfinished sheared metal edges or other sharp parts on bicycles that are, or may be, exposed to hands or legs; sheared metal edges that are not rolled shall be finished so as to remove any feathering of edges, or any burrs of spurs caused during the shearing process.

(c) *Integrity.* There shall be no visible fracture of the frame or of any steering, wheel, pedal, crank, or brake system component resulting from testing in accordance with: The hand-brake loading and performance test, § 1512.18(d); the foot brake force and performance test, § 1512.18(e); and the road test, § 1512.18(p) (or the sidewalk bicycle proof test, § 1512.18(q)).

(d) *Attachment hardware.* All screws, bolts, or nuts used to attach or secure components shall not fracture, loosen, or otherwise fail their intended function during the tests required in this part. All threaded hardware shall be of sufficient quality to allow adjustments and maintenance. Recommended quality thread form is specified in Handbook H28, "Screw Thread Standards for Federal Service,"¹ issued by the National Bureau of Standards, Department of Commerce; recommended mechanical properties are specified in ISO Recommendation R898, "Mechanical Properties of Fasteners," and in ISO Recommendations 68, 262, and 263, "General Purpose Screw Threads."²

(e) [Revoked].

(f) [Revoked].

(g) *Excluded area.* There shall be no protrusions located within the area bounded by (1) a line 89 mm (3½ in) to the rear of and parallel to the handlebar stem; (2) a line tangent to the front tip of the seat and intersecting the seat mast at the top rear stay; (3) the top surface of the top tube; and (4) a line connecting the front of the seat (when adjusted to its highest position) to the junction where the handlebar is attached to the handlebar stem. The top tube on a female bicycle model shall be the seat mast and the down tube or tubes that are nearest the rider in the normal riding position. Control cables no greater than 6.4 mm (¼ in) in diameter and cable clamps made from material not thicker than 4.8 mm (⅜ in) may be attached to the top tube.

¹Copies may be obtained from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

²Copies may be obtained from: American National Standards Institute, 1430 Broadway, New York, New York 10018.

(h) [Revoked].

(i) *Control cable ends.* Ends of all control cables shall be provided with protective caps or otherwise treated to prevent unraveling. Protective caps shall be tested in accordance with the protective cap and end-mounted devices test, § 1512.18(c), and shall withstand a pull of 8.9 N (2.0 lbf).

(j) *Control cable abrasion.* Control cables shall not abrade over fixed parts and shall enter and exit cable sheaths in a direction in line with the sheath entrance and exit so as to prevent abrading.

§ 1512.5 Requirements for braking system.

(a) *Braking system.* Bicycles shall be equipped with front- and rear-wheel brakes or rear-wheel brakes only.

(b) *Handbrakes.* Handbrakes shall be tested at least ten times by applying a force sufficient to cause the handlebar to contact the handlebar, or a maximum of 445 N (100 lbf), in accordance with the loading test, § 1512.18(d)(2), and shall be rocked back and forth with the weight of a 68.1 kg (150 lb) rider on the seat with the same hand-brake force applied in accordance with the rocking test, § 1512.18(d)(2)(iii); there shall be no visible fractures, failures, movement of clamps, or misalignment of brake components.

(1) *Stopping distance.* A bicycle equipped with only handbrakes shall be tested for stopping distance by a rider of at least 68.1 kg (150 lb) weight in accordance with the performance test, § 1512.18(d)(2) (v) and (vi), and shall have a stopping distance of no greater than 4.57 m (15 ft.) from the actual test speed as determined by the equivalent ground speed specified in § 1512.18(d)(2)(vi).

(2) *Hand lever access.* Hand lever mechanisms shall be located on the handlebars in a position that is readily accessible to the rider when in a normal riding position.

(3) *Grip dimension.* The grip dimension (maximum outside dimension between the brake hand lever and the handlebars in the plane containing the centerlines of the handgrip and the hand brake lever) shall not exceed 89 mm (3½ in) at any point between the pivot point of the lever and lever midpoint; the grip dimension for sidewalk bicycles shall not exceed 76 mm (3 in). The grip dimension may increase toward the open end of the lever but shall not increase by more than 12.7 mm (½ in) except for the last 12.7 mm (½ in) of the lever. (See figure 5 of this Part 1512.)

(4) *Attachment.* Brake assemblies shall be securely attached to the frame by means of fasteners with locking devices such as a lock washer, lock-nut, or equivalent and shall not loosen during the rocking test, § 1512.18(d)(2)(iii). The cable anchor

bolt shall not cut any of the cable strands.

(5) *Operating force.* A force of less than 44.5 N (10 lbf) shall cause the brake pads to contact the braking surface of the wheel when applied to the handlebar at a point 25 mm (1.0 in) from the open end of the handlebar.

(6) *Pad and pad holders.* Caliper brake pad shall be replaceable and adjustable to engage the braking surface without contacting the tire or spokes and the pad holders shall be securely attached to the caliper assembly. The brake pad material shall be retained in its holder without movement when the bicycle is loaded with a rider of at least 68.1 kg (150 lb) weight and is rocked forward and backward as specified in the rocking test, § 1512.18(d)(2)(iii).

(7) [Revoked]

(8) *Hand lever location.* The rear brake shall be actuated by a control located on the right handlebar and the front brake shall be actuated by a control located on the left handlebar. The left-hand/right-hand locations may be reversed in accordance with an individual customer order. If a single hand lever is used to actuate both front and rear brakes, it shall meet all applicable requirements for hand levers and shall be located on either the right or left handlebar in accordance with the customer's preference.

(9) *Hand lever extensions.* Bicycles equipped with hand lever extensions shall be tested with the extension levers in place and the hand lever extensions shall also be considered to be hand levers.

(c) *Footbrakes.* All footbrakes shall be tested in accordance with the force test, § 1512.18(e)(2), and the measured braking force shall not be less than 178 N (40 lbf) for an applied pedal force of 310 N (70 lbf).

(1) *Stopping distance.* Bicycles equipped with footbrakes (except sidewalk bicycles) shall be tested in accordance with the performance test, § 1512.18(e)(3), by a rider of at least 68.1 kg (150 lb) weight and shall have a stopping distance of no greater than 4.57 m (15 ft) from an actual test speed of at least 16 km/h (10 mph). If the bicycle has a footbrake only and the equivalent groundspeed of the bicycle is in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute),³ the stopping distance shall be 4.57 m (15 ft) from an actual test speed of 24 km/h (15 mph) or greater.

(2) *Operating force.* Footbrakes shall be actuated by a force applied to the pedal in a direction opposite to that of

³This is proportional to a gear development greater than 6.67 m (21.9 ft) in the bicycle's highest gear ratio. Gear development is the distance the bicycle travels in meters, in one crank revolution.

the drive force, except where brakes are separate from the drive pedals and the applied force is in the same direction as the drive force.

(3) *Crank differential.* The differential between the drive and brake positions of the crank shall be not more than 60° with the crank held against each position under a torque of no less than 13.6 N-m (10 ft-lb).

(4) *Independent operation.* The brake mechanism shall function independently of any drive-gear positions or adjustments.

(d) *Footbrakes and handbrakes in combination.* Bicycles equipped with footbrakes and handbrakes shall meet all the requirements for footbrakes in § 1512.5(c), including the tests specified. In addition, if the equivalent ground speed of the bicycle is 24 km/h (15 mph) or greater (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute),³ the actual test speed specified in § 1512.18(e)(3) shall be increased to 24 km/h (15 mph) and both braking systems may be actuated to achieve the required stopping distance of 4.57 m (15 ft).

(e) *Sidewalk bicycles.* (1) Sidewalk bicycles shall not have handbrakes only.

(2) Sidewalk bicycles with a seat height of 560 mm (22 in.) or greater (with seat height adjusted to its lowest position) shall be equipped with a footbrake meeting all the footbrake requirements of § 1512.5(c), including the specified tests except that the braking force transmitted to the rear wheel shall be in accordance with the sidewalk bicycle footbrake force tests, § 1512.18(f).

(3) Sidewalk bicycles with a seat height less than 560 mm (22 in.) (with seat height adjusted to its lowest position) and not equipped with a brake shall not have a freewheel feature. Such sidewalk bicycles equipped with a footbrake shall be tested for brake force in accordance with the sidewalk bicycle footbrake force test, § 1512.18(f). Such sidewalk bicycles not equipped with brakes shall be identified with a permanent label clearly visible from a distance of 3.1 m (10 ft.) in daylight conditions and promotional display material and shipping cartons shall prominently display the words "No Brakes."

1512.6 Requirements for steering system.

(a) *Handlebar stem insertion mark.* The handlebar stem shall contain a permanent ring or mark which clearly indicates the minimum insertion depth of the handlebar stem into the fork assembly. The insertion mark shall not affect the structural integrity of the stem and shall not be less than 2½ times the stem diameter from the lowest point of the stem. The stem strength shall be maintained for at

least a length of one shaft diameter below the mark.

(b) *Handlebar stem strength.* The handlebar stem shall be tested for strength in accordance with the handlebar stem test, § 1512.18(g), and shall withstand a force of 2000 N (450 lbf) for bicycles and 1000 N (225 lbf) for sidewalk bicycles.

(c) *Handlebar.* Handlebars shall allow comfortable and safe control of the bicycle. Handlebar ends shall be symmetrically located with respect to the longitudinal axis of the bicycle and no more than 406 mm (16 in.) above the seat surface when the seat is in its lowest position and the handlebar ends are in their highest position.

(d) *Handlebar ends.* The ends of the handlebars shall be capped or otherwise covered. Handgrips, end plugs, control shifters, or other end-mounted devices shall be secure against a removal force of no less than 66.8 N (15 lbf) in accordance with the protective cap and end-mounted devices test, § 1512.18(c).

(e) *Handlebar and clamps.* The handlebar and clamps shall be tested in accordance with the handlebar test, § 1512.18(h). Directions for assembly of the bicycle required in the instruction manual by § 1512.19(a)(2) shall include an explicit warning about the danger of damaging the stem-to-fork assembly and the risk of injury to the rider that can result from overtightening the stem bolt or other clamping device. The directions for assembly shall also contain a simple, clear, and precise statement of the procedure to be followed to avoid damaging the stem-to-fork assembly when tightening the stem bolt or other clamping device.

§ 1512.7 Requirements for pedals.

(a) *Construction.* Pedals shall have right-hand/left-hand symmetry. The tread surface shall be present on both top and bottom surfaces of the pedal except that if the pedal has a definite preferred position, the tread surface need only be on the surface presented to the rider's foot.

(b) *Toe clips.* Pedals intended to be used only with toe clips shall have toe clips securely attached to them and need not have tread surfaces. Pedals designed for optional use of toe clips shall have tread surfaces.

(c) *Pedal reflectors.* Pedals for bicycles other than sidewalk bicycles shall have reflectors in accordance with § 1512.16(e). Pedals for sidewalk bicycles are not required to have reflectors.

§ 1512.8 Requirements for drive chain.

The drive chain shall operate over the sprockets without catching or binding. The tensile strength of the drive chain shall be no less than 8010

N (1,800 lbf) or 6230 N (1,400 lbf) for sidewalk bicycles.

§ 1512.9 Requirements for protective guards.

(a) *Chain guard.* Bicycles having a single front sprocket and a single rear sprocket shall have a chain guard that shall cover the top strand of the chain and at least 90° of the perimeter where the drive chain contacts the drive sprocket as shown in figure 7. The chain guard shall extend rearward to a point at least 8 cm (3.2 in.) forward of the centerline of the rear axle. The minimum width of the top area of the chain guard shall be twice the width of the chain in that portion forward of the rear wheel rim. The rear part of the top area may be tapered. The minimum width at the rear of the guard shall be one-half the chain width. Such chain guard shall prevent a rod of 9.4 mm (¾ in.) diameter and 76 mm (3.0 in.) length from entrapment between the upper junction of the chain and the sprocket when introduced from the chain side of the bicycle in any direction within 45° from a line normal to the sprocket.

(b) *Derailleur guard.* Derailleurs shall be guarded to prevent the drive chain from interfering with or stopping the rotation of the wheel through improper adjustments or damage.

§ 1512.10 Requirements for tires.

The manufacturer's recommended inflation pressure shall be molded into or onto the sidewall of the tire in lettering no less than 3.2 mm (¼ in.) in height. The statement of recommended inflation pressure shall be in the English language utilizing Arabic numerals. (The following language is suggested to indicate recommended inflation pressure: "Inflate to — PSI.") After inflation to 110 percent of the recommended inflation pressure, the tire shall remain intact on the rim, including while being tested under a load of 2,000 N (450 lbf) in accordance with the rim test, § 1512.18(j). Tubular sew-up tires, nonpneumatic tires, and nonmolded wired-on tires are exempt from this section.

§ 1512.11 Requirements for wheels.

(a) *Spokes.* There shall be no missing spokes.

(b) *Alignment.* The wheel assembly shall be aligned such that no less than 1.6 mm (⅛ in.) clearance exists between the tire and fork or any frame member when the wheel is rotated to any position.

(c) *Rims.* Rims shall retain the spokes and tire when side-loaded with 2000 N (450 lbf) and tested in accordance with the rim test, § 1512.18(j). Sidewalk bicycles need not meet this requirement.

§ 1512.12 Requirements for wheel hubs.

All bicycles (other than sidewalk bicycles) shall meet the following requirements:

(a) *Locking devices.* Wheels shall be secured to the bicycle frame with a positive lock device. Locking devices on threaded axles shall be tightened to the manufacturer's specifications.

(1) *Rear wheels.* There shall be no relative motion between the axle and the frame when a force of 1,780 N (400 lbf) is applied symmetrically to the axle for a period of 30 seconds in the direction of wheel removal.

(2) *Front wheels.* Locking devices, except quick-release devices, shall withstand application of a torque in the direction of removal of 17 N-m (12.5 ft-lb).

(b) *Quick-release devices.* Lever-operated quick-release devices shall be adjustable to allow setting the lever position for tightness. Quick-release levers shall be clearly visible to the rider and shall indicate whether the levers are in a locked or unlocked position. Quick-release clamp action shall emboss the frame or fork when locked.

(c) *Front hubs.* Front hubs not equipped with lever-operated quick-release devices shall have a positive retention feature that shall be tested in accordance with the front hub retention test, § 1512.18(j)(3), to assure that when the locking devices are released the wheel will not separate from the fork.

§ 1512.13 Requirements for front fork.

The front fork shall be tested for strength by application of at least 39.5 J (350 in-lb) of energy in accordance with the fork test, § 1512.18(k)(1), without visible evidence of fracture. Sidewalk bicycles need not meet this requirement.

§ 1512.14 Requirements for fork and frame assembly.

The fork and frame assembly shall be tested for strength by application of a load of 890 N (200 lbf) or at least 39.5 J (350 in-lb) of energy, whichever results in the greater force, in accordance with the frame test, § 1512.18(k)(2), without visible evidence of fracture or frame deformation that significantly limits the steering angle over which the wheel can be turned. Sidewalk bicycles are exempt from this section.

§ 1512.15 Requirements for seat.

(a) *Seat limitation.* No part of the seat, seat supports, or accessories attached to the seat shall be more than 125 mm (5.0 in.) above the top of the seat surface at the point where the seat surface is intersected by the seat post axis.

(b) *Seat post.* The seat post shall contain a permanent mark or ring that

clearly indicates the minimum insertion depth (maximum seat-height adjustment); the mark shall not affect the structural integrity of the seat post. This mark shall be located no less than two seat-post diameters from the lowest point on the post shaft, and the post strength shall be maintained for at least a length of one shaft diameter below the mark.

(c) *Adjustment clamps.* The seat adjustment clamps shall be capable of securing the seat in any position to which it can be adjusted and preventing movement of the seat in any direction under normal conditions of use. Following the road test, § 1512.18(p) (or the sidewalk bicycle proof test, § 1512.18(q), as applicable), the seat clamps shall be tested in accordance with the seat adjustment clamps and load test, § 1512.18(l).

§ 1512.16 Requirements for reflectors.

Bicycles shall be equipped with reflective devices to permit recognition and identification under illumination from motor vehicle headlamps. The use of reflector combinations off the center plane of the bicycle (defined in § 1512.18(m)(2)) is acceptable if each reflector meets the requirements of this section and of § 1512.18 (m) and (n) and the combination of reflectors has a clear field of view of $\pm 10^\circ$ vertically and $\pm 50^\circ$ horizontally. Sidewalk bicycles are not required to have reflectors.

(a) *Front, rear, and pedal reflectors.* There shall be an essentially colorless front-facing reflector, essentially colorless or amber pedal reflectors, and a red rear-facing reflector.

(b) *Side reflectors.* There shall be retroreflective tire sidewalls or, alternatively, reflectors mounted on the spokes of each wheel; the center of spoke-mounted reflectors shall be within 76 mm (3.0 in.) of the inside of the rim. Spoke-mounted reflectors shall be visible on each side of the wheel.

(c) *Front reflector.* The reflector or mount shall not contact the ground plane when the bicycle is resting on that plane in any orientation. The optical axis of the reflector shall be directed forward within 5° of the horizontal-vertical alignment of the bicycle when the wheels are tracking in a straight line, as defined in § 1512.18(m)(2). The reflectors and/or mounts shall incorporate a distinct, preferred assembly method that shall insure that the reflector meets the optical requirements of this paragraph (c) when the reflector is attached to the bicycle. The front reflector shall be tested in accordance with the reflector mount and alignment test, § 1512.18(m).

(d) *Rear reflector.* The reflector or mount shall not contact the ground

plane when the bicycle is resting on that plane in any orientation. The reflector shall be mounted such that it is to the rear of the seat mast with the top of the reflector at least 76 mm (3.0 in.) below the point on the seat surface that is intersected by the line of the seat post. The optical axis of the reflector shall be directed rearward within 5° of the horizontal-vertical alignment of the bicycle when the wheels are traveling in a straight line, as defined in § 1512.18(m)(2). The reflectors and/or mounts shall incorporate a distinct, preferred assembly method that shall insure that the reflector meets the optical requirements of this paragraph (d) when the reflector is attached to the bicycle. The rear reflector shall be tested in accordance with the reflector mount and alignment test, § 1512.18(m).

(e) *Pedal reflectors.* Each pedal shall have reflectors located on the front and rear surfaces of the pedal. The reflector elements may be either integral with the construction of the pedal or mechanically attached, but shall be sufficiently recessed from the edge of the pedal, or of the reflector housing, to prevent contact of the reflector element with a flat surface placed in contact with the edge of the pedal.

(f) *Side reflectors.* Reflectors affixed to the wheel spokes shall be mounted either flat on the spokes or within the spoke cage such that the angle between the optical axis and the normal to the plane of the wheel shall not exceed the angle of the spokes with the plane of the wheel. The reflectors shall not interfere with any wheel adjustments. The side-mounted reflector devices shall be essentially colorless or amber on the front wheel and essentially colorless or red on the rear wheel.

(g) *Reflector tests.* The pedal, front-mount, rear-mount, and side-mount reflectors shall be tested in accordance with the reflector test, § 1512.18(n), to assure the reflectance values over the angles given in tables 1 and 2.

(h) *Retroreflective tire sidewalls.* When retroreflective tire sidewalls are used in lieu of spoke-mounted reflectors, the reflecting material shall meet the following requirements:

(1) The retroreflective material shall form a continuous circle on the sidewall.

(2) The retroreflective material shall adhere to the tire such that after the tire has been subjected to a temperature of $50^\circ \pm 3^\circ \text{C}$ ($122^\circ \pm 5.4^\circ \text{F}$) for 30 minutes, the retroreflective material cannot be peeled or scraped away without removal of tire material.

(3) The retroreflective material shall be as resistant to abrasion as is the adjacent sidewall material so that when retroreflective material is removed from the inflated tire by abrasion with

a wet, steel bristle brush, tire material will be removed along with the retroreflective material.

(4) The retroreflective material shall be tested for performance in accordance with the retroreflective tire test, § 1512.18(o), to assure the reflectance properties over the angles given in table 3. When a portion of the retroreflective material is selected (and the remainder is masked as specified in § 1512.18(o)(2)(i)), the selected portion shall not contact the ground plane when the assembled bicycle is resting on that plane in any orientation.

§ 1512.17 Other requirements.

(a) *Road test.* Bicycles, other than sidewalk bicycles, shall be ridden at least 6.4 km (4.0 mi.) by a rider weighing at least 68.1 kg (150 lb.) and travel five times over a 30.5 m (100 ft.) cleared course in accordance with the road test, § 1512.18(p), and shall exhibit stable handling, turning, and steering characteristics without difficulty of operation. There shall be no system or component failure of the structure, brakes, or tires, and there shall be no loosening or misalignment of the seat, handlebars, controls, or reflectors during or resulting from this test.

(b) *Sidewalk bicycle proof test.* Sidewalk bicycles shall be dropped a distance of at least 300 mm (1.0 ft.) three times onto a paved surface with weights attached in accordance with the sidewalk bicycle proof test, § 1512.18(q). There shall be no fracture of wheels, frame, seat, handlebars, or fork during or resulting from this test.

(c) *Ground clearance.* With the pedal horizontal and the pedal crank in its lowest position and any training wheels removed, it shall be possible to tilt the bicycle at least 25° from the vertical without the pedal or any other part (other than tires) contacting the ground plane.

(d) *Toe clearance.* Bicycles not equipped with positive foot-retaining devices (such as toe clips) shall have at least 89 mm (3½ in) clearance between the pedal and the front tire or fender (when turned to any position). The clearance shall be measured forward and parallel to the longitudinal axis of the bicycle from the center of either pedal to the arc swept by the tire or fender, whichever results in the least clearance. (See figure 6 of this Part 1512.)

§ 1512.18 Tests and test procedures.

(a) *Sharp edge test.* [Reserved]

(b) [Revoked]

(c) *Protective cap and end-mounted devices test.* (Ref. § 1512.4(i), § 1512.6(d).) Any device suitable for exerting a removal force of at least 67 N (15 lbf) for protective caps and 8.9 N (2.0 lbf) for end caps at any point and in any direction may be used. All pro-

TECTIVE caps and end-mounted handlebar devices shall be tested to determine that they cannot be removed by application of the specified forces.

(d) *Handbrake loading and performance test.* (Ref. § 1512.5(b).)

(1) *Apparatus.* A spring scale or other suitable device for measuring the specified forces on the handbrake levers and a dry, clean, level, paved surface of adequate length.

(2) *Procedure.* The loading test, § 1512.18(d)(2)(i), and the rocking test, § 1512.18(d)(2)(iii), shall be performed before the performance test, § 1512.18(d)(2)(v), is performed and no adjustments shall be made between these tests.

(i) *Loading test procedure.* The hand levers shall be actuated with a force applied at a point no more than 25 mm (1.0 in) from the open end of the lever. If the hand lever contacts the handlebar (bottoms) before a force of 445 N (100 lbf) is reached, the loading may be stopped at that point, otherwise the loading shall be increased to at least 445 N (100 lbf).⁴ Application of the loading force shall be repeated for a total of 10 times and all brake components shall be inspected.

(ii) *Loading test criteria.* There shall be no visible fractures, failures, misalignments, and clearances not in compliance with applicable parts of § 1512.5.

(iii) *Rocking test procedure.* A weight of at least 68.1 kg (150 lb) shall be placed on the seat; the force required for the hand levers to contact the handlebars or 445 N (100 lbf), as determined in § 1512.18(d)(2), shall be applied to the hand levers;⁴ and the bicycle shall be rocked forward and backward over a dry, clean, level, paved surface at least six times and for a distance of at least 76 mm (3 in) in each direction.

(iv) *Rocking test criteria.* There shall be no loosening of the brake pads, pad holders, or cable and hand-lever securing devices or any other functional brake component.

(v) *Performance test procedure.* The following test conditions, unless otherwise specified in this Part 1512, shall be followed:

(A) The bicycle shall be ridden over a dry, clean, smooth paved test course free from protruding aggregate. The test course shall provide a coefficient of friction of less than 1.0 and shall have a slope of less than 1 percent.

(B) The wind velocity shall be less than 11 km/h (7 mph).

(C) Only the brake system under test shall be actuated.

(D) The bicycle shall attain the specified ground speed while the rider is in the normal riding position.

⁴For hand lever extensions, the loading shall be continued until a force of 445 N (100 lbf) is reached or the hand lever extension is in the same plane as the upper surface of the handlebars or the extension lever contacts the handlebars.

(E) The rider shall remain in the normal riding position throughout the test.

(F) The bicycle must be moving in a straight line at the start of brake application.

(G) Corrections for velocity at the initiation of braking may be made. The corrected braking distance shall be computed as follows:

$$S_c = (V_s/V_m)^2 S_m$$

where:

S_c = Corrected braking distance,

V_s = Specified test velocity,

V_m = Measured test velocity,

S_m = Measured braking distance.

The test run is invalid if at the commencement of the test, the measured test speed of the bicycle is not less than nor greater than the test speed required by this Part 1512 by 1.5 km/h (0.9 mph).

(H) Four test runs are required. The stopping distance shall be determined by averaging the results of the four test runs.

(I) The stopping distances specified are based on a rider weight of at least 68.1 kg (150 lb) and a maximum rider and weight combination of 91 kg (200 lb). Greater stopping distances are allowable for heavier riders and test equipment weights at the rate of 0.30 m per 4.5 kg (1.0 ft per 10 lb).

(J) A test run is invalid if front-wheel lockup occurs.

(vi) *Performance test criteria.* The stopping force applied to the hand lever at a point no closer than 25 mm (1.0 in) from the open end shall not exceed 178 N (40 lbf). Bicycles with an equivalent ground speed in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute)³ shall stop from an actual test speed of 24 km/h (15 mph) or greater within a distance of 4.57 m (15 ft); when the equivalent ground speed is less than 24 km/h (15 mph) under the same conditions, the bicycle shall stop from an actual test speed of 16 km/h (10 mph) or greater within a distance of 4.57 m (15 ft).

(e) *Footbrake force and performance test.* (Ref. § 1512.5(c) (1) and (2))

(1) *Apparatus.* Suitable devices for exerting and measuring the required forces and a dry, clean, level, paved surface of adequate length.

(2) *Force test.* The braking force shall be measured as the wheel is rotated in a direction of forward motion, and the braking force is measured in a direction tangential to the tire during a steady pull after the wheel completes one-half revolution but before the wheel completes one revolution. The brake shall be capable of producing a linearly proportional brake force for a gradually applied pedal force from 89 N to 310 N (20 to 70 lbf) and shall not be less than 178 N (40 lbf)

³See footnote 3 to § 1512.5.

for an applied pedal force of 310 N (70 lbf). All data points must fall within plus or minus 20 percent of the brake force, based on the measured brake load using the least square method of obtaining the best straight line curve.

(3) *Performance test.* The procedure of § 1512.18(d)(2)(v) shall be followed to test the footbrake performance. The stopping distance shall be less than 4.57 m (15 ft) from an actual test speed of 16 km/h (10 mph). In addition, if the equivalent ground speed of the bicycle is in excess of 24 km/h (15 mph) (in its highest gear ratio at a pedal crank rate of 60 revolutions per minute),³ the stopping distance shall be 4.57 m (15 ft) from an actual test speed of 24 km/h (15 mph) or greater.

NOTE.—No allowance shall be made for rider weight. See § 1512.5(d) for additional requirements for bicycles with both handbrakes and footbrakes.

(f) *Sidewalk bicycle footbrake force test.* For sidewalk bicycles, the footbrake force test is the same as for bicycles except; the brake force transmitted to the rear wheel shall continually increase as the pedal force is increased from 44.5 N to 225 N (10 to 50 lbf). The ratio of applied pedal force to braking force shall not be greater than two-to-one.

(g) *Handlebar stem test.* (Ref. § 1512.6(b))

(1) *Procedure.* The handlebar stem shall be tested for strength by applying a force of 2000 N (450 lbf), in a forward direction, for bicycles, or 1000 N (225 lbf) for sidewalk bicycles, at a point in line with the handlebar attachment point and at an angle of 45° from the stem centerline (See fig. 2).

(2) *Criteria.* No visible fractures shall result from this test.

(h) *Handlebar test.* (Ref. § 1512.6(e))

(1) *Stem-to-fork clamp test—(i) Procedure.* The handlebar and handlebar stem shall be assembled to the bicycle in accordance with the manufacturer's instructions. The handlebar-fork assembly shall be subjected to a torque applied about the axis of the stem, and shall then be disassembled and examined for signs of structural damage including cracking, splitting, stripping of threads, bearing damage, and bulging of the stem and fork structures. The handlebar and handlebar stem components shall be inspected for visible signs of galling, gouging, and scoring not due to normal assembly and disassembly operations.

(ii) *Criteria.* There shall be no visible movement between the stem and fork when a torque of 47+3, -0 N-m (35+2, -0 ft-lb) for bicycles and 20+3, -0 N-m (15+2, -0 ft-lb) for sidewalk bicycles is applied to the handlebar about the stem-to-fork axis. There shall be no visible signs of damage to the stem-to-fork assembly or any component part thereof.

(2) *Handlebar strength and clamp test—(i) Procedure.* The stem shall be in place on the bicycle or in an equivalent test fixture and secured according to manufacturer's instructions. A load shall be applied equally to each handlebar end in a direction to cause the greatest torque about the handlebar-to-stem clamp; deflection shall be measured along the line of applied force.

(ii) *Criteria.* The handlebars shall support a force of no less than 445 N (100 lbf) or absorb no less than 22.6 J (200 in-lb) of energy through a maximum deflection of no more than 76 mm (3.0 in.); the handlebar clamp shall prevent rotational movement of the handlebars relative to the clamp, and there shall be no visible fractures.

(i) *Pedal slip test.* [Reserved]

(j) *Rim test.* (Ref. §§ 1512.10 and 1512.11(c))

(1) *Procedure.* Only one wheel need be tested if the front and rear wheel are of identical construction. The wheel to be tested shall be removed from the bicycle and be supported circumferentially around the tire sidewall. A load of 2000 N (450 lbf) shall be applied to the axle and normal to the plane of the wheel for at least 30 seconds. If the wheel hub is offset, the load shall be applied in the direction of the offset.

(2) *Criteria.* The wheel and tire assembly shall be inspected for compliance with the requirements of § 1512.11(a) and shall be remounted on the bicycle according to the manufacturer's instructions and shall turn freely without roughness and shall comply with the requirement of § 1512.11(b).

(3) *Front hub retention test.* (Ref. § 1512.12(c))

(i) *Procedures.* Front hub locking devices shall be released. When threaded nuts and axles are used, the nuts shall be open at least 360° from a finger tight condition. A separation force of at least 111 N (25 lb) shall be applied to the hub on a line along the slots in the fork ends.

(ii) *Criteria.* The front hub shall not separate from the fork; fenders, mudguards, struts, and brakes shall not be allowed to restrain the separation.

(k) *Fork and frame test.* (Ref. §§ 1512.13 and 1512.14)

(1) *Fork test—(i) Procedure.* With the fork stem supported in a 76 mm (3.0 in) vee block and secured by the method illustrated in figure 1 of this Part 1512, a load shall be applied at the axle attachment in a direction perpendicular to the centerline of the stem and against the direction of the rake. Load and deflection readings shall be recorded and plotted at the point of loading. The load shall be increased until a deflection of 64 mm (2½ in) is reached.

(ii) *Criteria.* Energy of at least 39.5 J (350 in-lb) shall be absorbed with a deflection in the direction of the force of no more than 64 mm (2½ in.).

(2) *Fork and frame assembly test—(i) Procedure.* The fork, or one identical to that tested in accordance with the fork test, § 1512.18(k)(1), shall be replaced on the bicycle in accordance with the manufacturer's instructions; and a load of 890 N (200 lbf), or an energy of at least 39.5 J (350 in-lb), whichever results in the greater force, shall be applied to the fork at the axle attachment point against the direction of the rake in line with the rear wheel axle. The test load shall be counteracted by a force applied at the location of the rear axle during this test.

(ii) *Criteria.* There shall be no visible evidence of fracture and no deformation of frame that significantly limits the steering angle over which the front wheel can be turned.

(l) *Seat adjustment clamps and load test.* (Ref. § 1512.15(c))

(1) *Procedure.* A force of at least 668 N (150 lbf) shall be applied vertically downward (334 N (75 lbf) for sidewalk bicycles) to a point within 25 mm (1.0 in.) from either the front or rear of the seat, whichever produces the greatest torque on the seat clamp. After removal of this force, a force of 222 N (50 lbf) shall then be applied horizontally (111 N (25 lbf) for sidewalk bicycles) to a point within 25 mm (1.0 in.) from either the front or rear of the seat, whichever produces the greatest torque on the clamp.

(2) *Criteria.* No movement of the seat with respect to the seat post, or of the seat post with respect to the bicycle frame, shall have resulted from application of the forces specified.

(m) *Reflector mount and alignment test.* (Ref. § 1512.16 (c) and (d))

(1) *Procedure.* A force of 89 N (20 lbf) shall be applied to the reflector mount in at least three directions selected as most likely to affect its alignment. At least one of those directions shall be selected to represent a force that would be expected in lifting the bicycle by grasping the reflector.

(2) *Criteria.* (i) During test: The optical axis of the reflector shall remain parallel within 15° to the line or intersection of the ground plane and the center plane of the bicycle defined as a plane containing both wheels and the centerlines of the down tube and seat mast.

(ii) Post test: The optical axis of the reflector shall remain parallel within 5° to the line or intersection of the ground plane and the center plane of the bicycle defined as a plane containing both wheels and the centerlines of the down tube and seat mast.

(n) *Reflector test.* (Ref. § 1512.16(g))

(1) *Conditioning.* The following conditioning in the order given shall be

performed prior to testing for performance.

(i) *Warpage conditioning.* The reflector shall be held in a preheated oven for at least one hour at $50 \pm 5^\circ \text{C}$ ($122 \pm 5.4^\circ \text{F}$). A pedal reflector may be conditioned integrally with its pedal.

(ii) *Mechanical impact conditioning.* The reflector shall be mounted faceup in a manner similar to the way in which it is mounted on the bicycle. A 13 mm ($\frac{1}{2}$ in.) diameter polished steel ball shall be dropped normal to the center of the face of the reflector from a height of 0.76 m (30 in.). The ball may be guided by a tube with holes, but not restricted in free fall. Pedal reflectors are exempt from this impact conditioning.

(iii) *Moisture conditioning.* The reflector shall be submerged in tap water in a suitable container. The container shall be pressurized in 17.2 kN/m² (2.5 psi) (equivalent to 1.7 m (5% ft.) of water for 15 minutes and then released.

(2) *Reflector performance test.* (i) Arrangements for the reflector performance test shall be as shown in figure 3 and the distance D between the light source and the reflector shall be 30.5 m (100 ft.). The source of illumination shall be a lamp with a 51 mm (2.0 in.) effective diameter and a filament operating at $2,856 \pm 10$ percent color temperature. The observation point shall be colocated (as close as practicable) with the source of illumination. The reflector shall be mounted with the center of the reflector at the center of rotation and at the same horizontal level as the source of illumination. Photometric measurements shall be made at the observation angles and entrance angles given in tables 1 and 2.

(ii) The observation angle is the angle formed by a line from the point of observation to the center of the reflector with a second line from the center of the reflector to the source of illumination. The entrance angle is the angle between the optical axis of the reflector and a line from the center of the reflector to the source of illumination. The entrance angle shall be designated left, right, up, and down in accordance with the position of the source of illumination with respect to the axis of the reflector as viewed from behind the reflector when the plane of the observation angle is vertical and the receiver is above the source.

(iii) Photometric measurements shall be made either visually or photoelectrically. With either method, the light reflected to the observation point shall be determined. Also, the illumination on the reflector from the source shall be measured.

(iv) For visual measurements a comparison lamp, emitting light similar in

spectral quality to the reflector, shall be located adjacent to the reflector (at an angle not to exceed $\frac{1}{2}^\circ$) and arranged so that the candlepower can be varied from 0.01 to 0.25 to make the intensity duplicate that of the reflector under test. The candlepower of the source of the illumination of the reflector under test shall be known or determined for this test. Means shall be provided to change the intensity of the source of illumination without changing the filament color temperature. The comparison lamp shall be designed to avoid reflection from the source of illumination back in the direction of the observer. It shall be of such size and so diffused that when viewed by the observer (through a $2\frac{1}{2} \times$ reducing monocular), the candlepower can be readily compared and adjusted to that of the reflector. The observer shall have at least 10 minutes of dark adaption before making observations. For photoelectric measurements, the opening to the photocell shall not be more than $\frac{1}{2}$ inch vertical by 1 inch horizontal.

(v) Reflectors that mount on the bicycle in a fixed rotational position with respect to the bicycle, or the bicycle component on which they are mounted (such as pedals or spokes), shall be tested with a single orientation. Reflectors that do not mount on the bicycle in a fixed rotational position with respect to the bicycle shall be rotated about their axis through 360° to find the minimum candlepower per footcandle for each test point. If the measurement falls below the minimum requirement at any test point, the reflector shall be rotated $\pm 5^\circ$ about its axis from the angle where the minimum occurs, and the maximum candlepower per footcandle within this angle shall be the measured value.

(vi) Should uncolored reflections from the front surface interfere with photometric readings at any test point the lowest reading and location within 1° above, below, right, and left of the test point shall meet the minimum requirement for the test point.

(vii) A recommended coordinate system for definition of color is the "Internationale de l'Eclairage (CIE 1931)" system in the *IES Lighting Handbook*,⁵ fifth edition, 1972. In the coordinate system and when illuminated by the source defined in table 4 of this Part 1512, a reflector will be considered to be red if its color falls within the region bounded by the red spectrum locus and the lines $y0.980-x$ and $y0.335$; a reflector will be considered to be amber if its color falls within the region bounded by the yellow spectrum locus and the lines $y0.382$, $y0.790-0.667x$, and $y x-0.120$.

⁵ Copies may be obtained from Illuminating Engineering Society, 35 East 47th Street, New York, N.Y. 10017.

(c) *Retroreflective tire test.* (Ref. § 1512.16(h))

(1) *Apparatus.* Arrangements for the reflective intensity measurement shall be as shown in figure 3 of this Part 1512. A light projector (having a maximum effective lens diameter of $D/500$, where D is the distance from the source to the sidewall being measured) capable of projecting light of uniform intensity shall be used to illuminate the sample. The light falling on the sample shall have a color temperature of $2856 \text{K} \pm 10\%$ (equivalent to a tungsten filament lamp operated at a color temperature of $2856 \text{K} \pm 10\%$ having approximately the relative energy distribution given in table 4 of this Part 1512). The light reflected from the test surface shall be measured with a photoelectric receiver, the response of which has been corrected for the spectral sensitivity of the average photopic human eye. The dimensions of the active area of the receiver shall be such that no point on the perimeter of the receiver is more than $d/100$ from its center (where d is the distance from the receiver to the sidewall). Tires to be tested shall be mounted on a wheel, the rim and spokes of which have been masked in flat black so that when measured without the tire they indicate no appreciable reflectance. The tire shall be mounted and fully inflated. Distances shall be measured from the plane of the wheel and the center of the hub. For the tests, the distance D between the projector and the center of the wheel and distance d between the center of the wheel and the receiver shall each be at least 15 m (50 ft.).

(2) *Procedure*—(i) *Masking.* The reflecting strip to be tested shall be within two concentric circles, the larger of which is no more than 0.02 m (0.79 in.) greater in radius than the smaller. While additional reflecting material is permitted outside such boundaries, such additional material shall not be counted in determining the average width of the reflecting strip and shall be masked off with opaque, matte black tape in testing the reflecting material.

(ii) *Orientation.* With the tire mounted and inflated, every position of the reflecting strip to be tested shall be oriented so that the normal to this portion is within 40° of parallel to the axis of rotation of the wheel.

(iii) *Measurement.* Measure the distance d from the receiver to the center of the wheel and the minimum distance r from the axis of rotation of the wheel to the unmasked portion of the reflective strip. Measure the illumination incident on the reflective strip at uniform intervals of no more than 45° around the wheel, with the receiver oriented in the direction of the incident radiation. The average of

such readings will be the mean illumination of the sample *E*. If any one of such readings differs by more than 10 percent from the mean illumination, then a more uniform source must be obtained. Measure the illumination of the receiver due to reflection from the sidewall for each entrance angle and each observation angle given in table 3 of this Part 1512. The entrance angle and the observation angle shall be in the same plane. A negative entrance angle (figure 3 of this Part 1512) is specified when the entrance angle is small because the location of the receiver with respect to the direction of illumination becomes important for distinguishing between ordinary mirror-like reflection and retroreflection. The illumination incident on the test surface and the receiver shall be measured in the same units on a linear scale. Compute the ratio *A* for each combination of entrance angle and observation angle listed in table 3 as follows:

$$A = [(E_r/E_s) \times (d^2/r)]$$

Where:

A = Ratio in meters,

E_r = Illumination incident upon the receiver,

E_s = Illumination incident upon a plane perpendicular to the incident ray at the specimen position (see instructions above in this paragraph (o)(2)(iii) for averaging), measured in the same units as *E_r*,

d = The distance in meters from the receiver to the center of the wheel,

r = The minimum radius in meters of the boundary circles of the retroreflective strip.

The minimum value of *A* shall be that listed in table 3 of this Part 1512 for each combination of entrance angle and observation angle. The plane containing the entrance angle and the plane containing the observation angle shall coincide. In table 3, a positive entrance angle corresponds to the case in which the line of sight to the receiver lies between the line of incidence and the optic axis of the reflector, and a negative entrance angle corresponds to the case in which the line of incidence lies between the line of sight of the receiver and the optic axis of the reflector.

(iv) *Criteria*. The ratio *A* as defined in § 1512.18(o)(2)(iii) shall not be less than:

$$A = [4(\cos \theta / 1 + (\phi / 0.225)^2)]$$

where *A* is ratio in meters, θ is the entrance angle, and ϕ is the observation angle in degrees. The criterion applies only for entrance angles from 0° to 40° and observation angles from 0.2° to 1.5°, and performance is not specified beyond this range. The values of *A* in table 3 are obtained from the above formula by rounding up to two significant figures. Except in cases in which the performance of the reflector is seriously questionable, a reflector with *A* at least the value given in table 3 at each of the six combinations of en-

trance and observation angle will be considered to satisfy this criteria.

(p) *Road test*. (Ref. §§ 1512.15(c) and 1512.17(a)).

(1) *Procedure*. The bicycle shall be ridden at least 6.4 km (4.0 mi.) by a rider weighing at least 68.1 kg (150 lb.) with the tires inflated to maximum recommended pressure. Travel shall include riding the bicycle five times over a 30 m (100 ft.) course of wooden cleats fastened to a paved surface. The cleats shall be a full 25 mm (1.0 in.) high by 51 mm (2.0 in.) wide lumber with a 12 mm by 12 mm (½ in. by ½ in.) chamfer of 45° on the corners contacting the tires. The cleats shall be spaced every 1.8 m (6.0 ft.) over the 30 m (100 ft.) course. The bicycle shall be ridden over the cleated course at a speed of at least 24 km/hr (15 mph) with the rider firmly seated.

(2) *Criteria*. The bicycle shall exhibit stable handling, turning, and steering characteristics without difficulty of operation. There shall be no system or component failure of the structure, brakes, or tires and there shall be no loosening or misalignment of the seat, handlebars, controls, or reflectors.

(q) *Sidewalk bicycle proof test*. (Ref. §§ 1512.15(c) and 1512.17(b)).

(1) *Procedure*. The bicycle shall be loaded with weights of 13.6 kg (30 lb.) on the seat surface and 4.5 kg (10 lb.) attached to the end of each handle grip for a total load of 22.7 kg (50 lb.). The bicycle shall be lifted a distance of 0.3 m (1.0 ft.) and dropped (while maintaining an upright position) three times onto a paved surface. Following this and with weight removed, it shall be allowed to fall in any configuration and attitude from an upright position to the paved surface three times on each side.

§ 1512.19 Instructions and labeling.

A bicycle shall have an instruction manual attached to its frame or included with the packaged unit.

(a) The instruction manual shall include at least the following:

(1) Operations and safety instructions describing operation of the brakes and gears, cautions concerning wet weather and night-time operation, and a guide for safe on-and-off road operation.

(2) Assembly instructions for accomplishing complete and proper assembly.

(3) Maintenance instructions for proper maintenance of brakes, control cables, bearing adjustments, wheel adjustments, lubrication, reflectors, tires and handlebar and seat adjustments; should the manufacturer determine that such maintenance is beyond the capability of the consumer, specifics regarding locations where such maintenance service can be obtained shall be included.

(b) A bicycle less than fully assembled and fully adjusted shall have

clearly displayed on any promotional display material and on the outside surface of the shipping carton the following: (1) A list of tools necessary to properly accomplish assembly and adjustment, (2) a drawing illustrating the minimum leg-length dimension of a rider and a method of measurement of this dimension.

(c) The minimum leg-length dimension shall be readily understandable and shall be based on allowing no less than one inch of clearance between (1) the top tube of the bicycle and the ground plane and (2) the crotch measurement of the rider. A girl's style frame shall be specified in the same way using a corresponding boys' model as a basis.

(d) Every bicycle subject to the requirements of this Part 1512 and introduced into interstate commerce on or after May 11, 1976 through May 11, 1978, shall be labeled with the statement "Meets U.S. Consumer Product Safety Commission Regulations for Bicycles."

(1) Every such bicycle, displayed or offered for sale to consumers in a fully assembled condition, shall bear a label (such as a hang tag) at least 6.4 cm (2.5 in.) by 17.8 cm (7 in.) setting forth the required labeling statement legibly and conspicuously in capital letters at least 0.6 cm (0.25 in.) high. No other words or symbols may appear on the label. (See also § 1512.50.)

(2) The required labeling statement shall appear legibly and conspicuously in capital letters at least 1.3 cm (0.5 in.) high on the retail carton of every such bicycle offered for sale to consumers in an unassembled or partially assembled condition.

(e) Every bicycle subject to the requirements of this Part 1512 shall bear a marking or label that is securely affixed on or to the frame of the bicycle in such a manner that the marking or label cannot be removed without being defaced or destroyed. The marking or label shall identify the name of the manufacturer or private labeler and shall also bear some form of marking from which the manufacturer can identify the month and year of manufacture or from which the private labeler can identify the manufacturer and the month and year of manufacture. For purposes of this paragraph, the term "manufacture" means the completion by the manufacturer of a bicycle of those construction or assembly operations that are performed by the manufacturer before the bicycle is shipped from the manufacturer's place of production for sale to distributors, retailers, or consumers.

§ 1512.20 Separability.

If any section or portion thereof of this Part 1512 or its application to any person or circumstance is held invalid, the remainder of the section(s) and its (their) application to other persons or circumstances is not thereby affected.

[6355-01-C]

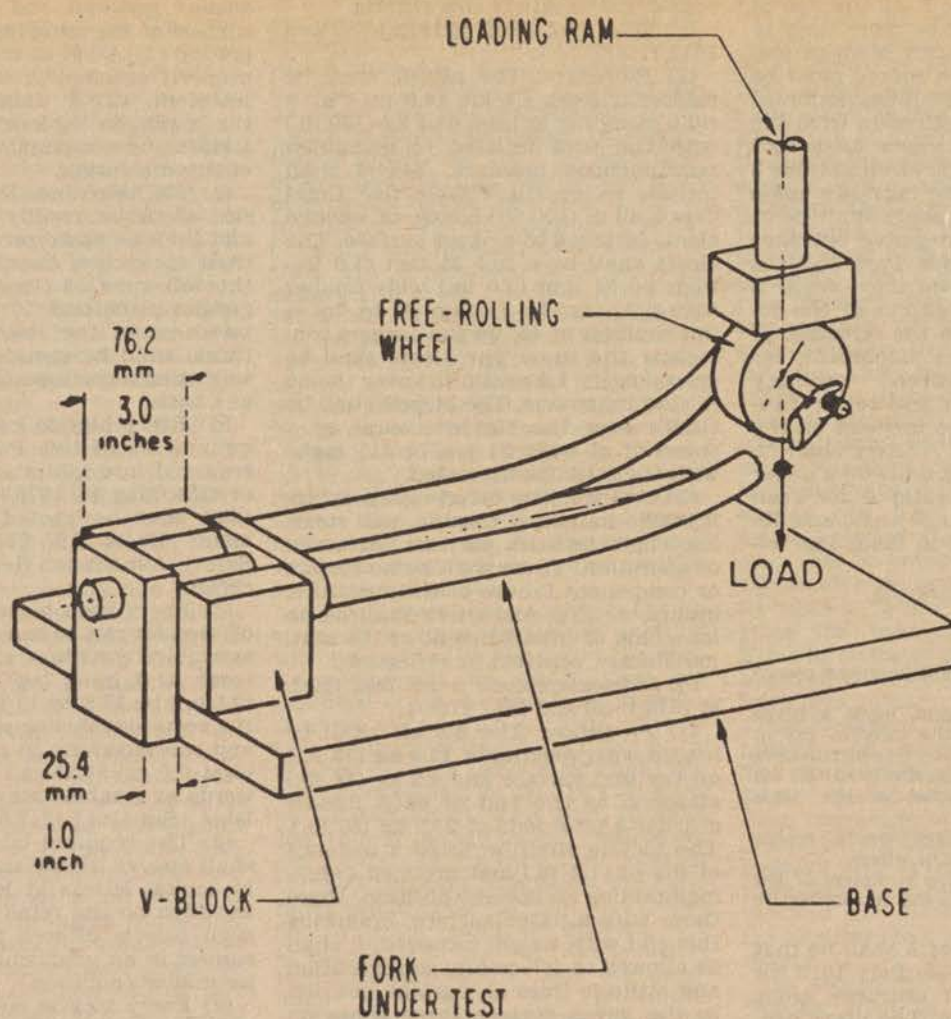


FIG 1-BICYCLE FRONT FORK
CANTILEVER BENDING TEST RIG

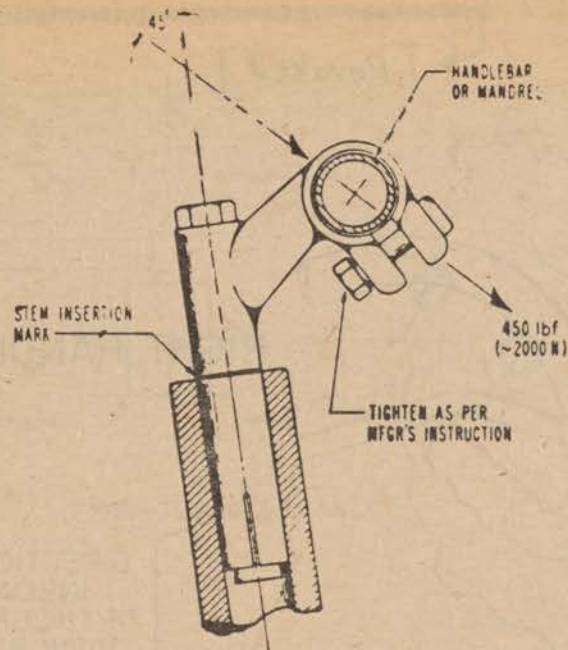
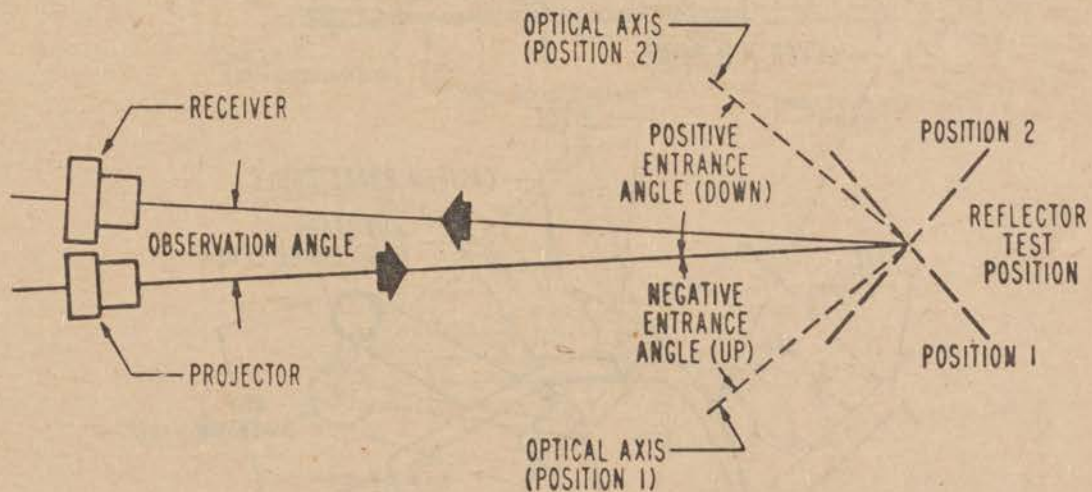


FIG 2—HANDLEBAR STEM LOADING

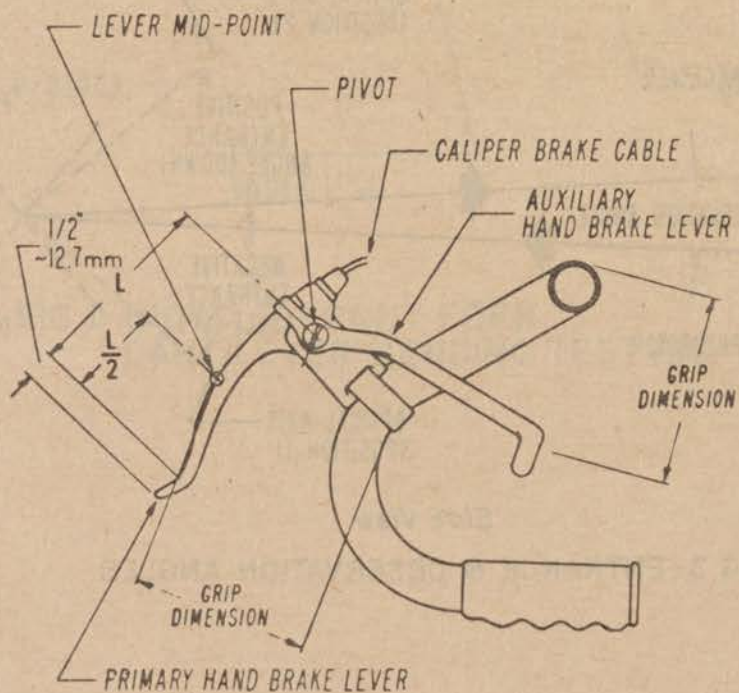
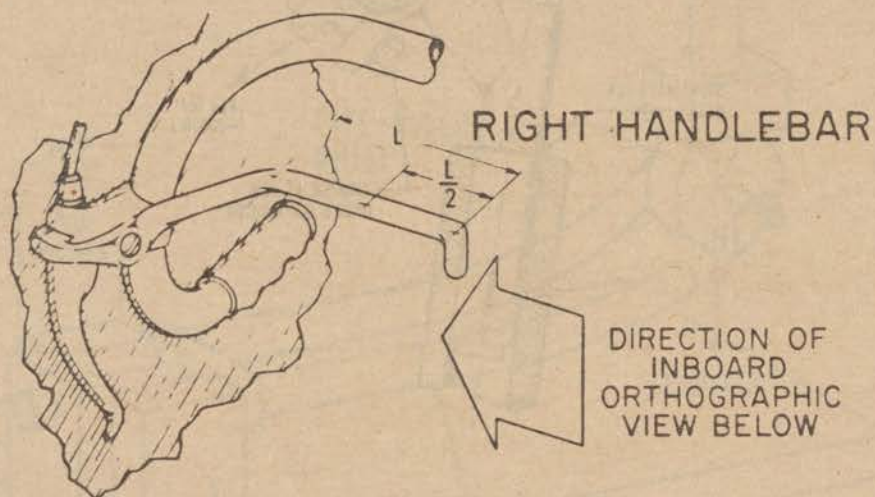


Side View

FIG 3—ENTRANCE & OBSERVATION ANGLES

FIG 4 - ~~TYPICAL INSTRUCTION EXAMPLES~~

[Revoked]

FIG 5-TYPICAL HANDBRAKE ACTUATOR
SHOWING GRIP DIMENSION

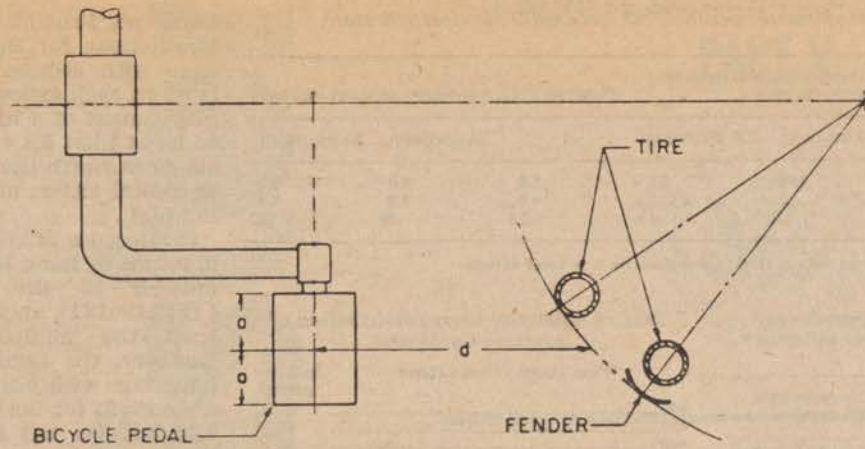


FIG 6-TOE CLEARANCE

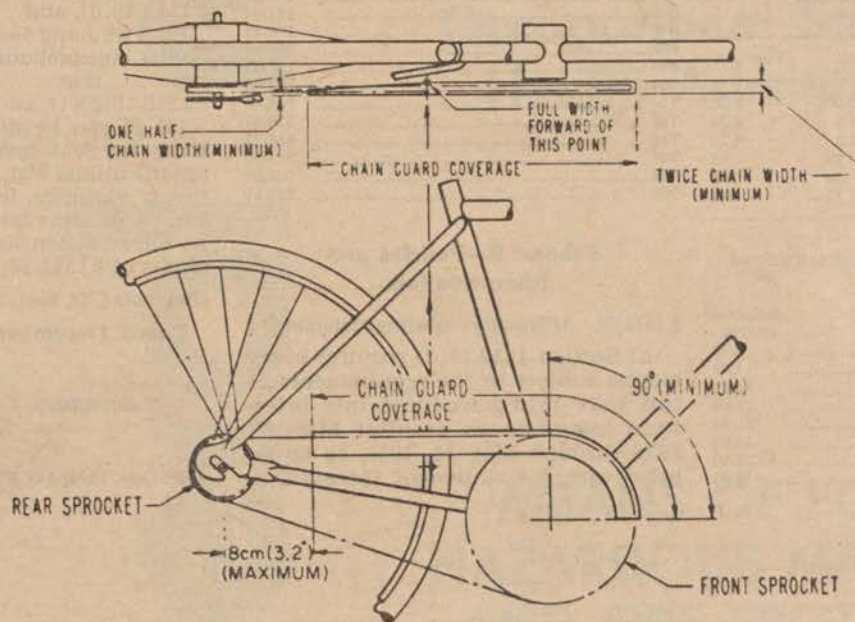


FIG 7-CHAIN GUARD REQUIREMENTS

TABLE 1.—Minimum candlepower per incident foot-candle for clear reflector¹

Observation angle	Front, rear, and side reflectors; entrance angle in degrees			Pedal reflectors; entrance angle in degrees		
	0	10 up/down	20 left/right	0	10 up/down	20 left/right
0.2	27.0	18.0	9.0	7.5	6.0	3.0
.3				6.0	4.8	2.4
1.5	.28	.20	.12	.28	.20	.12

¹ Amber values shall be $\frac{1}{2} \times$ clear values. Red values shall be $\frac{1}{4} \times$ clear values.TABLE 2.—Minimum candlepower per incident foot-candle for clear reflector¹

Observation angle	Front, rear, and side reflectors; entrance angle in degrees			
	30 left/right	40 left/right	50 left/right	
0.2	8.0	7.0	6.0	
1.5	.12	.12	.12	

¹ Amber values shall be $\frac{1}{2} \times$ clear values. Red values shall be $\frac{1}{4} \times$ clear values.

TABLE 3.—Minimum acceptable values for the quantity A defined in the retroreflective tire test procedure

Observation angle (degrees)	Entrance angle (degrees)	Minimum acceptable value of A	
		Meters	Feet
0.2	-4	2.2	7.25
.2	20	1.9	6.27
.2	40	1.3	4.29
1.5	-4	.22	.73
1.5	20	.19	.63
1.5	40	.13	.43

TABLE 4.—Relative energy distribution of sources

Wave length (nanometers)	Relative energy
380	9.79
390	12.09
400	14.71
410	17.68
420	21.00
430	24.67
440	28.70
450	33.09

TABLE 4.—Relative energy distribution of sources—Continued

Wave length (nanometers)	Relative energy
460	37.82
470	42.87
480	48.25
490	53.91
500	59.86
510	66.06
520	72.50
530	79.13
540	85.95
550	92.91
560	100.00
570	107.18
580	114.44
590	121.73
600	129.04
610	136.34
620	143.62
630	150.83
640	157.98
650	165.03
660	171.96
670	178.77
680	185.43
690	191.93
700	198.26
710	204.41
720	210.36
730	216.12
740	221.66
750	227.00
760	232.11

Subpart B—Policies and Interpretations

§ 1512.50 Affirmative labeling statement.

(a) Section 1512.19(d) requires every bicycle subject to the requirements of this Part 1512 introduced into interstate commerce on or after May 11, 1976 through May 11, 1978, to be labeled with the statement "Meets U.S.

Consumer Product Safety Commission Regulations for Bicycles." In accordance with section 1512.19(d)(1), the label on each assembled bicycle, which may consist of a hang tag, is required to be at least 6.4 cm. (2.5 in.) by 17.8 cm. (7 in.) with the labeling statement in capital letters at least 0.6 cm. (0.25 in.) high.

(b) Because of variances in the manufacture of hang tags, a finished tag, ordered to the specifications of § 1512.19(d)(1), may be slightly smaller than the minimum specifications. However, the Commission finds that hang tags with either length or width dimensions (or both) of no more than 0.32 cm. ($\frac{1}{8}$ in.) less than the prescribed requirements adequately provide the requisite degree of conspicuousness to consumers.

(c) Therefore, the Commission will consider bicycles otherwise in compliance with the provisions of Part 1512 to be in compliance with the requirements as to length and width of hang tags used to comply with labeling requirements under § 1512.19(d)(1) for purposes of enforcement if:

(1) The hang tag is correctly labeled with the required statement under § 1512.19(d), and

(2) The hang tag meets all of the labeling conspicuousness, legibility, and type size requirements of § 1512.19(d)(1), and

(3) It can be documented that the hang tag was ordered to the correct specifications but, due to a manufacturing variance, is no more than 0.32 cm. ($\frac{1}{8}$ in.) smaller in either or both of its linear dimensions than the requirements of § 1512.19(d)(1).

(Sec. 10(a), 74 Stat. 378; 15 U.S.C. 1269(a).)

Dated: December 15, 1978.

SADYE E. DUNN,
Secretary, Consumer Product
Safety Commission.

[FR Doc. 78-35447 Filed 12-21-78; 8:45 am]

FRIDAY, DECEMBER 22, 1978

PART V



**DEPARTMENT OF
LABOR**

**Occupational Safety and
Health Administration**

**MEANS OF EGRESS;
HAZARDOUS MATERIALS;
AND FIRE PROTECTION**

**Proposed Amendments and
Revisions to Safety Standards**

Registered Professional Engineer

[4510-26-M]

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[29 CFR Part 1910]

[Docket No. S-004]

OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Means of Egress; Hazardous Materials and Fire Protection; Proposed Amendments and Revisions

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Proposed Rulemaking.

SUMMARY: This notice contains proposed changes to three subparts in the present OSHA safety standards found in 29 CFR Part 1910. The specific subparts to be amended or revised are Subpart E—Means of Egress, Subpart H—Hazardous Materials, and Subpart L—Fire Protection.

The standards in Subpart E regulate the means of egress (emergency exits) from workplaces. The standards in Subpart H regulate the storage, handling and use of compressed gases (oxygen, hydrogen, and acetylene), flammable and combustible liquids, coating operations using flammable and combustible liquids (spraying and dipping), explosives and blasting agents, and the storage and handling of liquefied petroleum gases and anhydrous ammonia. The standards in Subpart L regulate portable fire suppression equipment (portable fire extinguishers and standpipe systems), fixed fire suppression systems (automatic sprinkler systems and various other fixed extinguishing systems), and local fire alarm signaling systems.

In Subpart E, OSHA proposes to change the wording of § 1910.37(n) to reference the applicable section of the proposed revision to Subpart L. Further, OSHA proposes to add two new definitions for terms used in Subpart E. Finally, OSHA proposes a new section, "Employee Fire Safety Plans," which would regulate the emergency action plan and the fire prevention plan that would be required in the proposed revisions to Subpart L. The changes proposed for Subpart E are predicated upon the proposed revisions to Subpart L. If the applicable sections in the proposed revisions to Subpart L are not adopted, these changes to Subpart E would not be necessary.

In Subpart H, OSHA proposes to amend the wording of certain provisions by changing the current references to certain National Fire Protection Association (NFPA) standards to

references to the applicable sections of the Subpart L proposal. These changes are necessary to coordinate referencing between Subparts H and L and will eliminate incorporation by reference in Subpart H. The Subpart H amendments, like those in Subpart E, are predicated upon the proposed changes to Subpart L.

In Subpart L, OSHA proposes to revise the present subpart for two reasons. First, it is necessary to update the present provisions which have been in effect since 1971. Since 1971 several changes have been made to the source national consensus standards and OSHA has received extensive comments from many affected parties concerning the effectiveness, applicability and relevance of the existing standards. OSHA's enforcement experience has revealed difficulties with certain provisions of Subpart L. Second, the Secretary of Labor and the Assistant Secretary for Occupational Safety and Health have expressed their commitment to undertake a thorough review of the agency's regulatory policy and to redirect its efforts toward more significant safety and health hazards. This proposal is part of that continuing commitment to reexamine the agency's regulatory activities and to set standards which more effectively achieve the goal and purpose of the Occupational Safety and Health Act.

DATES: Comments on these proposed rules must be received by March 16, 1979.

Requests for a hearing must also be received by March 16, 1979.

ADDRESS: Comments and requests should be sent to: Docket Officer, Docket S-004, Room S6212, U.S. Department of Labor, Washington, D.C. 20210.

FOR FURTHER INFORMATION CONTACT:

Mr. Michael B. Moore, Occupational Safety and Health Administration, Room N-3463, U.S. Department of Labor, Washington, D.C. 20210, 202-523-7225.

SUPPLEMENTARY INFORMATION

I. HISTORY.

Under section 6(a) of the Occupational Safety and Health Act of 1970 (the Act), Congress directed OSHA to promulgate safety and health standards from existing national consensus standards and established Federal standards. On May 29, 1971, OSHA promulgated its first occupational safety and health standards in 29 CFR Part 1910 (36 FR 10466). Subparts E, H, and L were included in this publication and became effective on August 27, 1971 and February 15, 1972.

After the initial standards package was promulgated, OSHA found it nec-

essary to amend specific provisions of the standards. For example, on January 9, 1974, at 39 FR 1437, Table L-3 in Subpart L was amended to permit 12-year hydrostatic test intervals for fire extinguishers with aluminum shells and § 1910.158(b)(3) was changed to extend the maximum lengths of fire hose to be used on standpipe systems. These changes were made to permit acceptable alternatives to the practices required in the standards.

During this period of time, OSHA received petitions calling for the recognition of other methods of providing employee safety than those contained in the original set of standards and for the amendment of its standards to cover only occupational safety and health concerns.

In 1975, OSHA decided to review Subpart L to determine if revision was necessary. A revision would reflect the changes made in the source national consensus standards and would respond to the petitions which had been received. On April 23, 1976, OSHA published a notice in the FEDERAL REGISTER at 41 FR 17255 announcing a standards revision procedure and requesting information and participation in public meetings relevant to revising Subpart L. The agency raised several general and specific issues at that time and invited the public to submit written comments on the issues presented prior to June 23, 1976. That deadline was later extended to July 20, 1976. In addition to the request for written comment, the agency held three separate public meetings in San Francisco, Dallas, and Boston during June 1976. The purpose of those meetings was to afford the public an opportunity to present oral as well as written comments concerning the issues raised in the April 23, 1976 FEDERAL REGISTER notice. The written comments received and the transcripts of these meetings and related exhibits have been entered into the OSHA record for this proposed rulemaking.

Upon completion of the public meetings and the close of the comment period, OSHA reviewed all the data presented and determined that the revision of Subpart L was necessary.

This notice contains proposed revisions and is applicable only to general industry workplaces. The maritime, construction and agricultural industries are covered by standards in separate parts of Chapter XVII of Title 29 of the Code of Federal Regulations.

In early 1977, OSHA initiated a program to revoke certain general industry standards which were determined to be unrelated to employee safety. In general, the standards selected for revocation were among those which were obsolete or inconsequential, concerned with comfort or convenience, directed

toward public safety or property protection, subject to enforcement by other regulatory agencies, contingent on manufacturers' approval or recommendations, encumbered by unnecessary detail or adequately covered by other general standards. The list of proposed revocations was published in the FEDERAL REGISTER at 42 FR 62734 on December 13, 1977 and the public was given an opportunity to present their views on the proposal. Certain provisions of Subparts E, H and L contained in this notice of proposed rule-making were included in the December 13, 1977 notice.

On October 24, 1978 OSHA published a notice in the FEDERAL REGISTER at 43 FR 49726 revoking certain standards which OSHA determined could be revoked without adversely affecting employee safety and health. The standards which were revoked on October 24, 1978, have not been addressed in this notice.

II. BACKGROUND

(1) PHILOSOPHY

During the development of this proposal many persons have questioned the need for a standard covering fire protection equipment and practices in the workplace.

There are two contrasting points of view concerning OSHA's involvement in fire protection in the workplace. The first is that the hazards to employees when they are permitted to fight fires with equipment required by OSHA is too great and that employees should be evacuated from the fire scene to prevent injury or loss of life. Proponents of this philosophy believe that in requiring fire protection equipment, OSHA permits employees to be exposed to a hazardous situation and that this is contrary to the purposes of the Act. These persons believe that firefighting is better left to the municipal or county firefighter.

The second point of view is that some fire protection by trained employees is necessary for the welfare of the employee, the employer and the economy. The proponents of this philosophy believe that since firefighting is necessary to protect life and property, the tools and equipment to be used by trained employees should be regulated so that they are maintained and installed in a safe and reliable manner.

OSHA believes that there is a definite life safety hazard associated with fire in the workplace. OSHA recognizes that there is a need for employees to fight fires in workplaces, especially where no public fire protection service is available or where available service is inadequate. The purpose of Subpart L is to provide standards for fire protection equipment and practices so that employees are protected from the hazards associated with fire

in the workplace when the employees must provide fire protection services.

(2) ISSUES

In its FEDERAL REGISTER notice of April 23, 1976, OSHA raised several issues related to safety and fire protection. The notice requested written comments on the issues.

Comments received in response to the notice were used in the development of this proposal. OSHA now invites comments on this proposal to assist in the development of the final standard.

A summary of the major responses to the April 1976 FEDERAL REGISTER notice is given below:

1. *Whether particular standards contained in Subpart L should be revoked because they have little, if any, relevance to employee safety in the workplace and relate to property protection or safety of the general public?* OSHA received many comments addressing this issue. Most of the comments supported revision of the subpart rather than a total revocation. The comments calling for total revocation stated that the standards in Subpart L are property protection oriented and lack relevance to employee safety. The comments calling for revision recognized the need for the standards, but cited several problem areas and difficulties such as out-of-date standards. OSHA is proposing to revise the standards and believes that most of the property protection oriented standards have been revoked through the FEDERAL REGISTER notice published on October 24, 1978. This proposal should eliminate all other property protection standards.

2. *Whether particular provisions of the standards need simplification or clarification?* Almost all of the comments received on this issue called for simplification and clarification. Comments substantiate the position that simplified standards would require less interpretation by eliminating ambiguous language. This in turn would lead to more uniform enforcement. In light of the comments and in furtherance of OSHA's commitment to promulgate more effective standards, OSHA believes that Subpart L should be revised to be clearer and easier to understand. We have included a proposed appendix to enhance understanding of Subpart L.

3. *Whether particular provisions of Subpart L should set forth specifications which must be met by employers or should, rather, require a level of performance which would ensure employee safety without requiring specific means of meeting that performance level?* The majority of comments received on this issue called for performance-type standards. Supporters of performance language cited the flexi-

bility provided by such language as being advantageous. Those commenters who wanted specification-type standards indicated that they wanted to be told specifically what to do. In order to attain a goal of flexibility OSHA is proposing a performance-type revision to Subpart L. For those persons who want to know exactly what to do to assure they are in compliance, OSHA proposes a nonmandatory appendix of compliance guidelines.

4. *Whether there are any gaps in OSHA's coverage of fire protection which could lead to unsafe working conditions?* Several gaps were identified in the comments. The two most frequently cited were the lack of training for persons expected to use fire protection equipment and the lack of personal protective equipment standards for fire brigade members. OSHA has addressed all of the gaps identified in the comments.

5. *How should ANSI and NFPA standards be utilized in Subpart L?* Most commenters stated that OSHA should continue using the national consensus standards but that we should incorporate them by reference. Other commenters cited OSHA's inability to keep up with current editions of the source standards as being disadvantageous to the program. OSHA is proposing to use the source standards as nonmandatory compliance guidelines and to include them in the appendix to the standards. These guidelines would supplement the performance-type standards proposed in the revision. As discussed more fully below, since these guidelines are nonmandatory and only established one of several possible ways of complying with the mandatory performance standards, they could be changed or added to as new procedures are developed without rulemaking.

6. *Whether Subpart L should, in and of itself, require the use of fixed and portable fire suppression and alarm systems and equipment, or whether it should simply be referenced when fire protection devices are required by other OSHA standards?* Comments stated that OSHA's fire protection standards should apply only to those systems required by the present Subpart L standards.

OSHA is proposing that Subpart L contain the design and installation criteria for fire protection equipment and systems. The proposed standards could be referenced for their criteria when fire protection systems or equipment are required in OSHA standards. For example, if an OSHA standard were to require the installation of a particular fire protection system, that standard could reference Subpart L for design and installation criteria in-

stead of having to state them in the standard.

7. *Whether OSHA should continue to allow the use of inverting type portable fire extinguishers?* Some commenters stated that OSHA should phase-out these types of units. Other commenters stated that only certain types of these units should be phased out. However, some comments stated that the units are not hazardous as long as they are properly inspected and maintained. OSHA agrees with those commenters who believe that certain units are not hazardous if properly maintained and inspected; however, other types of units can be subjected to metal fatigue and creep under the pressure of hydrostatic testing or use. It is this type of fatigue that can lead to rupture of the unit and possible injury or death to employees. For this reason OSHA has proposed the phase-out of soldered or riveted shell inverting type units.

8. *Whether OSHA should prohibit carbon tetrachloride and chlorobromomethane?* The majority of commenters called for the prohibition of these units because of the toxic byproducts which are generated when the agent strikes hot metal surfaces. The agents have also been shown to be toxic when inhaled, absorbed or otherwise taken into the body. Injury data received in support of the comments further supports prohibition. Only a few comments state there is no hazard associated with these chemicals if they are used in properly ventilated areas. OSHA agrees with the majority of commenters and is proposing the prohibition of the use of these chemicals as extinguishing agents because of their toxicity. In addition, other safer agents are readily available.

9. *Whether OSHA should require a mounting height of portable fire extinguishers and, if so, what should it be?* In the FEDERAL REGISTER notice of October 24, 1978, OSHA revoked paragraph 1910.157(a)(6) which required a specific mounting height for portable fire extinguishers. OSHA is proposing a performance requirement that portable fire extinguishers be accessible to employees.

10. *Whether OSHA should accept fixed automatic fire extinguishing systems in lieu of portable fire extinguishers?* Comments indicated that portable equipment complements fixed systems and should be used in conjunction with fixed systems. OSHA is proposing a set of standards which would be applicable to both fixed and portable extinguishing systems. The appropriate system to be used in any particular case would depend on the specific hazard situation and on the requirements of the standards covering the type of situation.

11. *Whether portable fire extinguishers should be required only along the means of egress routes so that they should only be used to aid employees in escaping from the hazards?* Many comments stated that portable units should be distributed throughout the workplace because more effective protection is provided through shorter travel distances. Other comments stated that employees retrieving units mounted along the means of egress would interfere with orderly evacuation of other employees. OSHA agrees with those commenters who believe that such placement would interfere with the evacuation of employees. Further, placement of extinguishers along the means of egress could lead to placement of units throughout the workplace because, for some employees, the means of egress would carry them through the building. Therefore, OSHA is proposing to require the placement of fire extinguishers at locations where they will be readily accessible to employees who are to use them. This would include special hand trucks or powered vehicles located where members of the plant fire brigade can reach them at the time of a fire emergency.

12. *Whether OSHA should require variable stream nozzles with shut-offs?* The majority of comments received on this issue indicated the need for shut-off nozzles to give employees control of the water supply at the nozzle-end of a hose line. Employee injury due to contact with "whipping" hose can occur when employees lay a flowing open bore nozzle on the ground. Other commenters believed that open bore nozzles can provide adequate employee safety if used by trained employees. OSHA is proposing to require shut-off nozzles because they give the nozzle operator more control of the water supply. While a variable stream nozzle having the capability to vary a water stream from a fog to a straight stream provides a highly effective piece of fire fighting equipment, OSHA does not believe they are necessary in all installations. Therefore, OSHA is not proposing a requirement for variable stream nozzles.

13. *Whether OSHA should accept a hose system in lieu of portable fire extinguishers, and, if so, what type?* Many comments stated that small-hose (1-1/2") installed in accordance with the applicable NFPA standard can provide employee protection equivalent to that provided by portable fire extinguishers. Supporters cited factors such as increased water supply and extended reach of the hose stream as advantageous. OSHA is proposing to accept portable fire hose systems in lieu of portable fire extinguishers since fire hose systems have a greater water supply and because of

the extended range of the hose systems over portable fire extinguishers covering the same area.

14. *Whether unlined linen or hemp hose should be prohibited by OSHA?* Some comments called for the prohibition of such hose because existing standards do not contain adequate requirements for inspection and maintenance of standpipe hose systems. Other comments stated that such hose is adequate if properly maintained and inspected. OSHA is proposing the prohibition of such hose when it becomes defective and can no longer provide service.

15. *Whether OSHA should establish maintenance and testing requirements for fire hose, and if so, what should they be?* Many comments called for some type of maintenance and testing requirements to assure the reliability of the hose. Comments cited field experience with fire hose which contains holes caused by poor maintenance. To limit the possibility of employee injury due to the existence of defective hose, OSHA is proposing to adopt the appropriate requirements of the NFPA standards for maintenance and inspection of fire hose.

16. *Whether total flooding systems using agents hazardous to employees should be regulated by OSHA; and if so, whether predischage alarms, evacuation and rescue plans, and maintenance requirements should be addressed?* Comments supported the need for safety devices on total flooding systems to ensure employee safety in areas protected by total flooding systems using hazardous agents. Comments suggested the use of such devices as predischage alarms and rescue equipment. Where there is the possibility of employee entrapment in areas which are protected by this type of fixed systems, OSHA is proposing to require predischage alarms, instruction signs, and employee rescue equipment. In order to assure the reliability of this equipment, OSHA is also proposing maintenance and testing requirements for the equipment.

17. *Whether OSHA should allow alternatives to manual pullbox alarms such as whistles, voice, visual or tactile communication systems?* Almost all of the comments addressing this issue supported alternative methods of providing employee alarms. Comments gave examples of the appropriateness of visual alarms in areas where persons have difficulty hearing and tactile alarms where persons may be unable to see or hear present alarm systems. Other comments stated that alarms such as steam whistles and air horns are in use at the present time and can provide adequate safety. In consideration of the comments, OSHA is proposing to accept alternative alarm systems.

18. Whether OSHA requirements for frequent tests of fire alarm signal systems are necessary when the systems are provided with supervisory circuits? How often should unsupervised systems be tested? Several comments started that the weekly test requirement is too burdensome because of its frequency. Comments suggested that the test interval be every two months. In recognition of the comments presented, OSHA is proposing a two-month test interval for all alarm systems. This would assure the reliability of the system without presenting an unnecessary burden on employers.

19. Whether a single universal fire evacuation signal should be required, and if so, what should it be? Comments addressing this issue urged OSHA to delay such a requirement as it is still being studied and debated on an international level. As there has been no determination made of what type of signal would be required and because installation of such a signal would involve retrofitting existing workplaces, OSHA has not proposed a single universal fire evacuation signal at this time.

In addition to the above issues on which OSHA invites further public comment, several other issues are also relevant to the proposal. Therefore, OSHA is also seeking comment, information and evidence on the following issues:

a. Whether employees should be permitted to be exposed to concentrations of slightly toxic extinguishing agents and, if so, what should the maximum exposure level be?

b. Whether smoke-vents can contribute to employee safety during a fire emergency? If so, should OSHA have requirements for them?

c. Whether portable fire extinguishers should be permitted to be placed directly on the floor surface in certain locations where the floor remains dry and free of corrosive agents?

d. Whether single source water supplies for sprinkler, standpipe, and water spray systems are adequate for employee safety and, if so, in what type of workplaces?

e. Whether OSHA should phase-out all types of soda-acid and foam inverting-type extinguishers or only those with riveted or soldered brass shells?

f. Whether small garden type or booster type hose ($\frac{1}{2}$ " to 1") can provide adequate fire control for incipient stage fires in lieu of small hose ($1\frac{1}{2}$ ") as proposed in this standard?

g. Whether the impact testing of head protective devices in accordance with the NFPCA document, "Model Performance Criteria for Structural Firefighters' Helmets, August 1977" is adequate with respect to impact at the top of the head protective device, or should OSHA, in addition, continue to

require impact testing in accordance with ANSI Z89.1, *Requirements for Industrial Head Protection*?

h. Whether the circulating air oven test for heat resistance of protective head devices as contained in the NFPCA document, "Model Performance Criteria for Structural Firefighters' Helmets" is adequate or should the test procedure be more detailed?

i. Whether the proposed training requirements for brigade members are adequate and, if not, what constitutes an adequate training program for members of a fire brigade?

j. Whether OSHA should establish test procedures and performance levels for high temperature criteria for self-contained breathing apparatus used by firefighters and, if so, what should they be?

k. Whether the proposed standard for fire brigades should include test criteria for gloves which address cut resistance and thermal insulation against radiant heat energy? If the test criteria should be included, is the test method contained in the NIOSH publication "Development of Criteria for Firefighters' Gloves; Volume II: Glove Criteria and Test Methods, 1976" sufficient, or should other test criteria be developed?

l. Whether OSHA should require all total flooding extinguishing systems to be equipped with supervisory monitoring systems?

(3) THE STANDARD'S NEW FORMAT

OSHA is proposing a new format for the standards which are being revised. The format is presented for the first time in this proposal and consists, in general, of performance type standards accompanied by a nonmandatory appendix of compliance guidelines and additional information. This new format has been developed as a result of OSHA's efforts to promulgate performance type standards while providing specific compliance guidelines and as a response to suggestions offered by the public during the comment period following OSHA's April 23, 1976 notice in the *FEDERAL REGISTER*.

OSHA has received considerable comment in the past about the problems associated with standards which, for example, set specific mounting heights for fire extinguishers, specific heights for guardrails, specific distances between flammable liquid storage tanks and other similarly detailed specifications. Many of the commenters have complained about the extra expense they have incurred when moving extinguishers or raising guardrails mere inches to comply with OSHA standards when the method they had previously used provided adequate employee safety. In order to resolve many of the problems associat-

ed with specification standards, OSHA has considered using performance type standards whenever possible or otherwise provide flexibility for compliance in this proposal.

However, there are cases when specifications are necessary to achieve the goals of employee safety. Some commenters have complained that their biggest problem with OSHA standards is not knowing exactly what is expected of them. These commenters indicate they need specifications to be able to measure their success in complying with OSHA's standards and to minimize different interpretations. Generally, these commenters are small businesses without the safety expertise found in larger corporate safety staffs. In order to provide the employer and employee with additional information and to provide guidelines for compliance, OSHA is considering the use of a nonmandatory appendix containing various methods of compliance that an employer could use to comply with the intent of the OSHA standard.

OSHA is presenting this proposal in the new format so that interested parties may comment on the usefulness and practicality of such a format. The mandatory standard itself would contain performance or goal-oriented language directed at providing compliance flexibility and the nonmandatory appendix would contain guidelines directed at providing some methods of compliance which would meet the intent of the OSHA performance standard.

It is emphasized that the appendix is nonmandatory and is provided for guidance. It is intended to provide useful, explanatory material and information to employers and employees to aid in understanding and complying with the standards. The information contained in the appendix does not create any additional obligations or detract from any obligations of the standard. In view of the nature of the appendix, changes could subsequently be made without rulemaking.

III. SUMMARY AND EXPLANATION OF THE PROPOSAL

(1) SUBPART E—MEANS OF EGRESS

Section 1910.35—Definitions. OSHA is proposing to add two new definitions to §1910.35. In new paragraph (i), OSHA proposes to define the term "emergency action plan." In paragraph (j), OSHA proposes to define the term "emergency escape." These paragraphs define new terms used in the proposal.

Section 1910.37—Means of egress, general. OSHA is proposing to amend paragraph 1910.37 (n) to reference Subpart L for maintenance and testing criteria for fire alarm signaling systems. This proposal would eliminate the need for employers and employees

to refer to a second document to determine the requirements.

Section 1910.38—Employee emergency plans. Section 1910.38 is presently titled "Specific means of egress requirements by occupancy" and is reserved. OSHA proposes to change the title to "Employee emergency plans" and to propose standards in this section for employee action plans and fire prevention plans.

In paragraph (a), Emergency action plans, the proposal contains the standards necessary for the employer to develop an emergency action plan which would satisfy the exemption criteria in §1910.157 or other requirements of Subpart L. The emergency action plan would consist of and address all designated actions and duties incumbent upon employers and employees to ensure employee safety during an emergency evacuation from a workplace where an emergency hazard exists. The proposed section contains requirements for the plan's elements and its implementation. It also calls for alarm systems, training, and total or partial evacuation at the time of emergency.

In paragraph (b), Fire prevention plan, the proposal contains the standards necessary to minimize unwanted fires in the workplace. It would address all areas of the workplace where combustibles may accumulate in order to control or prevent the likelihood of unwanted fire. The proposed section contains the elements of a fire prevention plan and requirements for housekeeping, training and maintenance of fire suppression systems.

These two new paragraphs are necessary to provide regulation of employee fire safety plans which can be used in complying with the proposed requirements of Subpart L.

(2) SUBPART H—HAZARDOUS MATERIALS

Section 1910.107—Spray finishing using flammable and combustible materials. In paragraph 1910.107(f)(1) OSHA proposes to change the referenced standard from NFPA 13-1969 to 29 CFR 1910.159.

Section 1910.108—Dip tanks containing flammable or combustible liquids. In paragraph 1910.108(g)(1) OSHA proposes to change the referenced standard from NFPA 10-1970 to 29 CFR 1910.157.

In Paragraph 1910.108(g)(2) OSHA proposes to change the referenced standard from NFPA 15-1969 to 29 CFR 1910.163.

In Paragraph 1910.108(g)(3) OSHA proposes to change the referenced standard from NFPA 11-1970 to 29 CFR 1910.163.

In Paragraph 1910.108(g)(4) OSHA proposes to change the referenced standard from NFPA 12-1968 to 29 CFR 1910.162.

In Paragraph 1910.108(g)(5) OSHA proposes to change the referenced standard from NFPA 17-1969 to 29 CFR 1910.161.

Section 1910.109—Explosive and blasting agents. In paragraph 1910.109(d)(7)(i) OSHA proposes to change the referenced standard from NFPA 13-1969 to 29 CFR 1910.159.

In Paragraph 1910.109(d)(7)(ii) (a) OSHA proposes to change the referenced standard from NFPA 10-1970 and NFPA 14-1970 to 29 CFR 1910.157 and 29 CFR 1910.158 respectively.

All of the above changes to Subpart H, Hazardous Materials, are made for simplification and clarification of the standards and to eliminate the need for employers and employees to refer to a source apart from other OSHA standards.

(3) SUBPART L—FIRE PROTECTION

Section 1910.156—Definitions. OSHA proposes an expansion to this section to contain not only the present definitions but also the scope and application statements for the subpart. This addition is necessary to make clear that the revised Subpart L applies only to workplaces in general industry and does not apply to the construction and maritime industries which are subject to fire protection requirements in their respective parts.

Further, OSHA proposes definitions for the following terms: Aqueous film-forming foam, approved, automatic fire detection device, combination detector, flame detector, heat detector, line-type detector, other fire detectors, smoke detectors, spot-type detector, carbon dioxide, discharge alarm, dry chemical, dry powder, education, extinguisher classification, extinguisher rating, fixed extinguishing system, foam, gaseous agent, Halon 1211, Halon 1301, inspection, local application system, maintenance, multipurpose dry chemical, pre-action or pre-discharge alarm, sprinkler alarm, sprinkler system, Class II standpipe system, Class III standpipe system, total flooding system, training, after-flame, basic plane, buddy breathing device, fire brigade, flame resistance, helmet, incipient stage fire, interior structural fire fighting, lining, outer shell, positive pressure breathing apparatus, quick disconnect valve, and vapor barrier. The above definitions would clarify and simplify certain terms in the proposed revision.

Section 1910.157—Portable Fire Extinguishers. As a result of the comments received, OSHA is proposing substantial changes to the existing format of this section. It is noted that this section requires that portable fire extinguishers be installed in all workplaces, unless the workplace comes within the limited exemption provided in paragraph (b) of this section.

The proposed changes reflect our efforts to eliminate those standards which are advisory or which bear little relevance to employee safety.

In order to accommodate the proposed changes to this standard, OSHA has found it necessary to reorganize certain existing paragraphs so that new paragraphs can be placed where they most logically belong. The proposed reorganization of §1910.157 is as follows:

Paragraph (a), "General requirements," would become paragraph (a), "Scope and application."

Paragraph (b), "Selection of extinguishers," would become paragraph (b), "Exemptions."

Paragraph (c), "Distribution of portable fire extinguishers," would become paragraph (c), "General requirements."

Paragraph (d), "Inspection, maintenance, and hydrostatic testing," would become paragraph (d), "Selection and distribution."

A new paragraph (e) would be added and would be titled "Inspection, maintenance and testing."

A new paragraph (f) would be added and would be titled "Hydrostatic testing."

A new paragraph (g) would be added and would be titled "Training and education."

OSHA proposes a new scope and application paragraph for paragraph (a) of this section. The new paragraph would establish which provisions of the section are applicable to fire extinguishers installed on the inside of workplace buildings and structures and which provisions are applicable to units installed on the outside of workplace buildings and structures. Portable fire extinguishers which are located inside would be subject to the entire section whereas extinguishers for employee use installed outside would only have to meet the maintenance, inspection, and testing requirements of this section. The reason for the limited coverage of the outside extinguishers is that the hazard to employees that is presented by the build-up of toxic gases, smoke, and heat on the inside of workplace buildings and structures is not present in the exterior work environment.

In the new paragraph (b), Exemptions, OSHA proposes to provide an exemption from the requirements of this section for those employers who select the option for total evacuation at the time of a fire emergency. Many comments have suggested that such an optional exemption should be acceptable for those employers who would rather evacuate all employees than permit them to fight fires. To obtain an exemption from this section, the employer would have to develop and implement an effective fire safety

program which would include the total evacuation of all employees from the workplace at the time of a fire emergency. In such cases the provision of portable fire equipment in the workplace would obviously not be for employee use and therefore OSHA would have no need to require or regulate that equipment.

However, in all cases where the employer has provided portable extinguishers in the workplace, OSHA believes that some type of control on the maintenance, inspection, testing and distribution of those extinguishers is necessary to assure employee safety and health. It is in those cases that this section is necessary and relevant to employee safety and health.

In paragraph 1910.157(c)(1) OSHA is proposing to permit the mounting of portable fire extinguishers at any location, provided they are easily accessible to employees without subjecting the employee to the possibility of injury. To do this, OSHA is combining the wording of several of the present standards into one performance type standard.

In paragraph (c)(2) OSHA is keeping its present requirement that all extinguishers be approved for their expected use. There are no proposed changes to this requirement.

OSHA, in paragraph (c)(3), is proposing for the first time, the prohibition of carbon tetrachloride and chlorobromomethane extinguishing agents. This proposed prohibition is based on the toxicity of these two vaporizing liquids when they are used in extinguishing fires.

Paragraph (c)(4) contains OSHA's present requirement that extinguishers be maintained in fully charged and operable condition and kept in their designated place at all times except during use. There are no proposed changes to this requirement.

In paragraph (c)(5) OSHA is proposing a phaseout of certain extinguishers which operate by inverting the extinguisher to initiate an uncontrolled pressure generating chemical reaction to expel the agent. This type of extinguisher, commonly referred to as the soda-acid type, has been shown to cause severe injury and, in some cases, death to the operators when the extinguisher ruptures during use.

In paragraph (d) OSHA is proposing to permit as much flexibility in extinguisher selection and distribution as possible while assuring employee safety and health. Many of the present standards have been eliminated because they only contain suggestions and because they bear little or no relevance to employee safety.

The most significant change in the selection and distribution portion of the standard is the transfer of the extinguisher distribution tables to the

appendix. OSHA proposes to keep the maximum employee travel distances to an extinguisher the same as in the present standard; however, OSHA is deleting distribution requirements based on square feet area because travel distances provide sufficient guidelines for distribution.

Paragraphs (d)(1) and (d)(2) contain the present OSHA standards for Class A extinguisher travel distance and general selection criteria. There have been no proposed changes in these requirements.

OSHA is proposing in paragraph (d)(3) to recognize small hose stations as acceptable substitutes for Class A portable fire extinguishers.

OSHA believes that, for the purpose of employee safety, small hose stations can provide protection equal to or better than that of a Class A unit and for that reason total substitution is acceptable. OSHA believes that those employees who have been designated and trained as fire brigade members can put a small hose station into service and extinguish or control an incipient stage fire as well as they could with Class A portable fire extinguishers. The small additional amount of time that it takes to place a hose system into service is adequately compensated for by the extended range and discharge times associated with the hose system.

Paragraphs (d)(4) and (d)(5) contain the present travel distance requirements for Class B and Class C units. There are no proposed changes to these requirements.

Paragraph (d)(6) contains a proposed new requirement for a 75-foot employee travel distance to Class D extinguishers because previous standards did not address Class D hazards and because Class D fires present a growth rate similar to Class A fires.

OSHA proposes to add a new paragraph (e) to §1910.157 which would contain the maintenance and inspection requirements. The proposed improvements to the maintenance and inspection paragraph have been made to add certain requirements to further assure that fire extinguishers provided in the workplace for employee use are maintained in a safe condition. By improving and clarifying the maintenance and inspection criteria, OSHA hopes to eliminate the potential of employee injury due to unsafe fire extinguishers.

OSHA is proposing a new paragraph (f) which would contain requirements for hydrostatic testing. This paragraph would contain the updated requirements for hydrostatic testing found in NFPA 10-1977.

OSHA is proposing another new paragraph (g) which would contain the new training and education requirements. The need for these new

requirements was identified in the public comments submitted to OSHA.

OSHA is proposing annual training and education of employees who are expected to use portable fire extinguishers as part of their work assignment. Training would include education and "hands-on" training with portable units so that employees would be aware of how an extinguisher acts when it is discharged. Education would include instruction in how extinguishers work and how they should be operated. Education could include either classroom instruction or paycheck envelope notices.

Section 1910.158—Standpipe and hose systems. OSHA is proposing to revise this section to clarify and to update certain provisions based on changes to the source consensus standard.

The proposed changes to this section would contribute to employee safety and health by improving the criteria for the installation and maintenance of standpipe and hose systems installed for employee use.

OSHA has found it necessary to reorganize this section so that the proposed standards follow a logical sequence. The proposed reorganization is as follows:

Paragraph (a), "General requirements," would become paragraph (a), "Scope and application."

Paragraph (b), "Hose outlets" would become paragraph (b), "Protection of standpipes."

Paragraph (c), "Water supplies" would become paragraph (c), "Equipment."

Paragraph (d), "Tests and maintenance" would become paragraph (d), "Water supply."

A new paragraph (e), "Tests and maintenance" would be added.

In the new paragraph (a) OSHA proposes to limit the coverage of the section to those Class II and Class III standpipe systems installed to meet a particular OSHA standard.

OSHA in not addressing Class I standpipe systems because standards related to them were revoked on October 24, 1978.

Paragraph (b) contains the present standard for the protection of standpipes. There have been no proposed changes to this standard.

Paragraph (c)(1) contains the present standards for hose closets and cabinets and there are no proposed changes to the requirement.

Paragraph (c)(2) contains some of the present standards for hose outlets. The remainder of the present standards have either been modified to meet the most recent edition of the source standard or have been deleted because they apply to Class I systems.

Paragraph (c)(3)(i) contains the present requirement for attachment of

fire hose to outlets with the provisions for Class I service removed. There is no change to the intent of the requirement.

OSHA is proposing in paragraph (c)(3)(ii), a requirement for lined hose on hose systems installed after July 1, 1980. The requirement would permit continued use of unlined hose on existing systems until it becomes unserviceable. At that point in time, the unlined hose would have to be replaced with lined hose. OSHA believes this requirement would eliminate the problems associated with poorly maintained unlined hose.

OSHA is proposing in paragraph (c)(3)(iii), to limit the length of fire hose attached to standpipe systems on the basis of friction loss rather than by setting specific lengths for lined and unlined hose. OSHA wants to ensure that the pressure available at the nozzle will be at least 30 psi (297 kPa). As long as this pressure is available, the length of the hose is not important.

OSHA is proposing in paragraph (c)(4), a requirement that all standpipe nozzles be equipped with shutoff nozzles after June 30, 1981. This type of nozzle permits the nozzle person to have better control over the hose.

Paragraph (d) would contain the present requirements for water supply.

Paragraph (e)(1)(i) would contain the present requirements for the hydrostatic testing of standpipe systems. There are no changes proposed to the present standard.

OSHA is proposing in paragraph (e)(1)(ii), a requirement for a hydrostatic test of fire hose prior to it being placed into service. The test would be conducted with the hose couplings in place to assure that they have been installed correctly. OSHA believes that, through such a requirement, defects such as poor coupling installation, hose manufacture, or leakage can be identified prior to use by the employee.

OSHA is proposing in paragraph (e)(2), requirements for the maintenance of standpipe systems. OSHA believes that a maintenance program will assure that standpipe systems provided in the workplace for employee use will be ready for use in the event of a fire emergency.

Section 1910.159—Sprinkler systems. OSHA is proposing to revise this section to eliminate coverage of some types of sprinkler systems even when they are provided in the workplace and to update the present standard.

To accomplish this, OSHA must reorganize this section so that the standard is presented in a logical sequence. The proposed reorganization of § 1910.159 is as follows:

Paragraph (a), "General requirements," would become paragraph (a) "Scope and application."

Paragraph (b), "Fire department connections," which has been revoked would become paragraph (b), "Exemptions."

Paragraph (c), "Sprinkler alarms," would become paragraph (c), "General requirements."

Paragraphs (d) and (e) would be eliminated.

OSHA is proposing in paragraph (a), a new scope and application paragraph.

OSHA has recognized that some sprinkler systems are installed solely for protection of property and stored materials. Such systems could include those used for in-rack storage protection or warehouse storage protection. Employee exposure to the fire hazard in these cases is usually limited if employees have been instructed to evacuate the workplace immediately upon sprinkler alarm or discharge. Once the employees have evacuated the workplace, the sprinkler systems would be serving a property protection function.

OSHA does not want to encourage the shutting down of sprinkler systems installed only for property protection which do not meet our present criteria. Such a step could be taken by an employer who cannot afford to bring a system into full compliance with the present OSHA standard.

Therefore, OSHA is proposing in paragraph (a)(1) to regulate only those sprinkler systems installed for employee safety.

Sprinkler systems installed for purposes such as extending travel distances to exits would be an example of such a system to be covered by this standard. Sprinkler systems requires by other OSHA standards would also be covered by these proposed standards.

Instead of requiring the employer to continually update the design of his sprinkler systems installed prior to the date of this proposed revision, OSHA would in paragraph (a)(2) recognize compliance with NFPA and NBFU standards for automatic sprinkler systems in effect at the time of installation for all existing automatic sprinkler systems as evidence of complying with the intent of this standard providing employees are not exposed to a recognized hazard.

OSHA is proposing in paragraph (b), an exemption for those systems installed for the sole purpose of providing property protection.

OSHA is proposing as paragraph (c), those general requirements necessary to ensure the reliability of a sprinkler system's design and installation.

Paragraph (c)(1) is a performance type requirement which would state that sprinkler systems be capable of

providing adequate protection and that only approved equipment and devices be used to comply with the standard.

Paragraph (c)(2) contains the present requirement for proper maintenance of the system. The paragraph has been rewritten, but does not alter the requirement.

Paragraph (c)(3) would state that employers be able to show that proper acceptance tests have been conducted on OSHA required sprinkler systems. Such tests would assure that systems operate as designed.

OSHA proposes in paragraph (c)(4), a requirement for at least one automatic water supply. This is the same as the present requirement; however, OSHA further proposes to require either an auxiliary water supply or an evacuation plan for protected areas when the primary supply is out of service. OSHA would also limit auxiliary supplies to those systems having more than 20 sprinklers. The new proposed requirements would ensure continued employee protection in cases where primary water supplies are unavailable for some reason.

OSHA proposes in paragraph (c)(5), to permit the attachment, at the end of sprinkler pipes of wet-pipe systems, of small hose for firefighting purposes. The current edition of the National Fire Protection Association's Standard for Automatic Sprinkler Systems, NFPA No. 13-1976, permits such attachments under certain conditions.

OSHA is proposing in paragraph (c)(6), a requirement to protect sprinklers from freezing.

Paragraph (c)(7) contains a requirement which would require the installation of sprinkler systems in a manner which would provide for drainage of water to enhance maintenance.

Paragraph (c)(8) would prohibit torch cutting for modifying or repairing sprinkler systems.

Paragraph (c)(9) would contain requirements for the style and type of sprinklers permitted on certain systems.

Paragraph (c)(10) would contain the present requirement for water flow alarms but would limit the alarm to systems having more than 20 heads.

Paragraph (c)(11) would provide for sprinkler spacing and clearances. OSHA is proposing a vertical clearance of 18" between heads and obstructions below the heads to permit proper distribution of water.

Paragraph (c)(12) would require a means of identification of hydraulically designed sprinkler systems.

Section 1910.160—Fixed extinguishing systems. This section has been rewritten to include design and installation requirements for all fixed extinguishing systems installed to meet OSHA requirements and to provide

clarity and conformity with newer source standards. It is intended to place the general requirements for installation and design of fixed systems into one paragraph rather than repeat them under each specific fixed extinguishing systems section. The specific sections would contain only those requirements which are relevant to employee safety and health and which concern the type of agent used in the system.

This proposed section contains general requirements taken from all of the present sections on specific fixed systems and are rewritten for clarity. There would be no change in the coverage in the present general requirements.

OSHA proposes in paragraph (a), a scope and application statement stating that this section applies to all fixed extinguishing systems installed to meet a particular OSHA standard. Total flooding systems, which pose a potential health or safety hazard to employees, would be covered in all cases regardless of the reason for which they were installed. OSHA does not propose to regulate those systems installed for property protection and where there is no employee exposure.

OSHA is proposing in paragraph (b)(1), a requirement that fixed extinguishing systems and components be designed and approved for the hazard they protect.

OSHA is proposing in paragraph (b)(2) that adequate temporary fire protection be provided when an OSHA required fixed system is inoperative.

OSHA proposes in paragraphs (b)(3) and (b)(4), certain alarms for the discharge of agent and for the prevention of re-entry into areas made hazardous by system discharge.

OSHA proposes in paragraph (b)(5), the labeling or posting of work areas which can become hazardous by the discharge of the fixed system in that area.

OSHA proposes in paragraph (b)(6), an annual inspection for each system to determine if the system is in proper operating condition.

Paragraphs (b)(7), (b)(8), and (b)(9) contain requirements found in the present standards for fixed systems. They have no proposed changes other than being relocated to this section.

Paragraph (b)(10) contains a proposed requirement that employees designated to inspect, maintain, operate or repair fire extinguishing systems be trained and informed in the functions they are to perform.

OSHA proposes in paragraph (b)(11), a ban on the use of carbon tetrachloride and chlorobromomethane as extinguishing agents in systems used to meet OSHA standards for the same reasons as discussed under the fire extinguisher section.

Paragraphs (b)(12) through (b)(19) are proposed to provide reliable system operation and have been adopted from the NFPA standards applicable to fixed extinguishing systems.

OSHA is proposing in paragraph (b)(20) that the means of egress from a discharge area be in accordance with Subpart E of the part.

OSHA also recognizes that there is a special hazard to employees associated with total flooding systems. Therefore, OSHA is proposing in paragraph (c) of this section to regulate those total flooding systems with potential health or safety hazards to employees. The proposed paragraph would set requirements for maximum safe concentrations of agent, emergency action plans and predischage alarms. All of these provisions are necessary to provide adequate employee protection from possible entrapment in total flooding discharge areas.

OSHA believes that the general requirements proposed above are necessary to ensure adequate employee protection from the hazards associated with unreliable or inadequate fixed fire suppression systems.

Section 1910.161—Fixed extinguishing systems, dry chemical. Section 1910.161, as it is presently written, is proposed to be revoked. The occupational hazards associated with carbon dioxide extinguishing systems which are presently covered by §1910.161 would be covered by the proposed revisions to §1910.162 of this subpart.

The proposed revisions to §1910.161 contain requirements for dry chemical fixed extinguishing systems. Some of the proposed requirements are new and some are the same as those found in §1910.160 of the present standard.

OSHA is proposing in paragraph (a), a scope and application statement for dry chemical extinguishing systems installed for employee protection.

OSHA is proposing in paragraph (b), specific requirements for dry chemical extinguishing systems. These proposed requirements would supplement the general requirements of proposed §1910.160, and they would address specific hazards related only to dry chemical systems.

In paragraph (b)(1) OSHA is proposing a requirement that dry chemical agents be approved by an agency acceptable to OSHA, for their intended use. This would ensure that an agent would provide adequate employee safety.

In paragraph (b)(2) OSHA proposes a requirement that would prohibit the mixing together of dry chemicals made of different compositions. Such mixtures can cause a pressure build-up inside of the storage container which could lead to a stressing of the cylinder beyond acceptable limits.

In paragraph (b)(3) OSHA proposes a requirement for predischage alarms in areas where employee vision could be impaired by system discharge. By providing a predischage alarm, the employer can evacuate employees before the system discharges and thereby assist employee evacuation.

In paragraph (b)(4) OSHA proposes a requirement for checking dry chemical storage cylinders to ensure that they are free of moisture. Moisture causes dry chemical to cake and thereby reduce the effectiveness of a systems discharge rate.

Section 1910.162—Fixed extinguishing systems, gaseous agent. Section 1910.162 of the present standards is reserved. OSHA proposes to use this section for standards relating specifically to fixed extinguishing systems which use gaseous agents.

New gaseous type agents have become available since the publication of the existing fire protection standards, and they present acceptable substitutes for agents such as carbon dioxide. OSHA is proposing new regulations in this section to cover these agents as well as to use the present requirements, which were found in §1910.161, to cover carbon dioxide systems. The most recent gaseous agents OSHA would recognize are Halon 1301 and Halon 1211.

OSHA is proposing in paragraph (a), a scope and application statement for fixed extinguishing systems using gaseous type extinguishing agents. Such systems would have to comply with the general requirements of §1910.160 and the specific requirements of this section.

In paragraph (b) OSHA proposes specific requirements for fixed extinguishing systems using gaseous type agents.

OSHA is proposing in paragraph (b)(1) that the agents used to supply fixed gaseous extinguishing systems be approved for the system's application. Such a requirement assures reliability of the system.

OSHA is proposing in paragraph (b)(2) that inert gaseous type extinguishing agents be maintained at sufficient concentration after discharge to extinguish a fire either by enclosure or by applying extra gas. This requirement would prevent the possibility of a reignition after employees have re-entered the workplace.

OSHA is proposing in paragraph (b)(3) that the concentration of agent used to extinguish surface fires be such that the development of toxic decomposition products be kept to a minimum. This requirement would ensure employee protection from inadvertent exposure to toxic levels of extinguishing agents.

OSHA is proposing in paragraph (b)(4) that the concentration of agents

used to extinguish deep-seated fires be capable of being maintained for at least seven minutes after initial discharge. In some cases, longer periods of time may be necessary to allow for the smoldering to be extinguished and the material to cool to a point where reignition is prevented. This requirement would eliminate the possibility of reignition after employees have reentered the workplace.

OSHA is proposing in paragraph (b)(5), a maximum discharge time of 30 seconds to reach the design concentration for total flooding systems because such a time limit would reduce the possibility of an incipient stage fire reaching a higher level of involvement.

OSHA is proposing in paragraph (b)(6), a requirement to maintain effective agent concentrations in areas where fire brigade members are providing emergency actions. This requirement would prevent possible entrapment of brigade members due to reignition of the fire.

In paragraphs (b)(7), (b)(8) and (b)(9) OSHA proposes limits for concentrations of acceptable gaseous agents. Employees would not be required to wear personal protective equipment if exposed to agent concentrations less than the proposed levels. OSHA would limit Halon 1301 concentration to 10%, and Halon 1211 or carbon dioxide concentrations to 4% if employees are exposed for a short period of time. In areas where employees would normally remain after discharge of the extinguishing agent, OSHA would limit Halon 1301 concentration to 7% and prohibit the use of Halon 1211 and carbon dioxide.

In paragraph (b)(10) OSHA proposes a performance type standard for the quantity of inert gaseous type extinguishing agent. This would permit flexibility in determining the quantity of gas necessary for employee protection.

Section 1910.163—Fixed extinguishing systems, water spray and foam. The present standards in §1910.163 apply to local fire alarm signaling systems. OSHA is proposing to change the title of the present section to "Fixed extinguishing systems, water spray and foam" and to transfer coverage of local fire alarm signaling systems to new §1910.164a of the proposal. The title change is necessary to provide a section for water spray and foam extinguishing systems which would follow the other fixed system requirements. The new requirements proposed in §1910.163 would cover fixed extinguishing systems using water spray or foam as the extinguishing agent. Automatic sprinkler systems would be covered by §1910.159 instead of this section.

In paragraph (a)(1) OSHA would propose a scope and application for the section. It would also exempt automatic sprinkler systems from coverage under this section because they are covered under §1910.159.

In paragraph (b) OSHA proposes specific requirements for foam and water spray systems. These specific requirements would supplement the general requirements found in §1910.160.

Paragraph (b)(1) would state that foams not be used to extinguish fires involving gases, cryogenic liquids or liquefied gases with boiling points below ambient workplace temperatures. Foam agents are ineffective on fires involving these fuels.

Paragraph (b)(2) would state that foams or water spray not be used to extinguish fires in materials which react violently with water.

Paragraph (b)(3) would state that regular foams not be used for polar solvent liquid fires. Regular foam is ineffective on this type of fire, and there are special foams designed and available for this purpose.

Paragraph (b)(4) would state that different types of foam shall not be mixed together. The chemical composition of various types of foam concentrates may be different and therefore incompatible. Such mixing may produce an ineffective agent and reduce the protection of employees.

Paragraph (b)(5) would prohibit the discharging of foams through spray devices onto fires involving water soluble solvents in depths exceeding one inch because discharging the agent in this manner may increase the size of the fire by causing the solvent to froth and overflow its container.

Paragraph (b)(6) would state the systems be designed to prevent a fire from reigniting. This would prevent the possibility of entrapment for fire brigade members performing clean-up or rescue operations.

Paragraph (b)(7) would state that drainage of water spray systems be directed to a location away from employee work areas to prevent employee exposure to flammable liquid or vapor runoff.

1910.164—Fire detection systems. OSHA proposes to use §1910.164, which is presently reserved for fire brigades, to contain the new requirements applicable to fixed detection systems. Fire brigades would be covered in §1910.165. OSHA is proposing to regulate those fixed detection systems installed to provide early warning of a workplace fire. These new requirements are not contained in the present standards, because there were no national consensus standards available when the initial standards were published. A national consensus standard, NFPA No. 72E—Automatic Fire Detectors, was published in 1974 and

these proposed requirements are based on that standard.

Paragraph (a) contains the scope and application statement for the section.

OSHA proposes in paragraph (b)(1) that all components and devices of fire detection systems be approved by an agency acceptable to OSHA to ensure their reliability.

OSHA proposes in paragraph (b)(2) that all fire detection systems be restored to normal operating condition after each test of the alarm system. This would ensure the reliability of the system and the continued protection of employees.

OSHA proposes in paragraph (d), requirements for protecting fire detectors from physical damage due to impact, corrosion or weather. The paragraph would also require adequate methods for mounting detectors.

In paragraph (e) OSHA proposes requirements for fire detector response time. OSHA is proposing performance-type criteria which would give employers and employees sufficient time to react to fires detected by the system.

In paragraph (f) OSHA proposes to require that the design and the distribution of fixed detection devices be based upon accepted engineering practices. This would ensure that the devices are reliable and adequate to provide protection of employees.

Section 1910.164a—Employee alarm systems. OSHA is proposing §1910.164a to provide new standards for employee alarm systems which would be used to inform employees of a fire or other hazardous emergency in the workplace. The new standards proposed in this section have been developed using the NFPA standards 72A, Local Protective Signaling Systems, 72B, Auxiliary Signaling Systems, 72C, Remote Station Signaling Systems, and 72D, Proprietary Signaling Systems. The section would provide for an effective alarm signaling system which would give employees sufficient time to safely evacuate.

In paragraph (a) OSHA is proposing a scope and application statement for the section which would give the coverage of the section.

OSHA is proposing in paragraph (b)(1) that an alarm system be installed in the workplace to provide sufficient reaction time to safely evacuate employees at the time of a life threatening emergency in the workplace.

OSHA proposes in paragraph (b)(2) that the alarm be capable of perception above ambient noise or light levels by all employees in the protected area. OSHA would also permit the use of tactile devices for those employees who would be unable to see or hear an alarm.

OSHA proposes in paragraph (b)(3) that the alarm be distinctive and recognizable as an emergency alarm.

OSHA proposes in paragraph (b)(4) that all employees be informed of the preferred method of sounding an emergency alarm.

OSHA is proposing in paragraph (c), requirements for the installation and restoration of alarm systems and components. OSHA would permit the use of steam whistles, air horns, strobe lights or tactile devices which have not been approved if the devices can provide adequate warning to all employees. OSHA recognizes that these types of devices are currently in use and that they can be expected to perform adequately if they are tested and maintained properly.

OSHA proposes in paragraph (d)(1) that all systems be maintained, installed and operated in the condition for which they are designed.

OSHA proposes in paragraph (d)(2) that the alarm system be tested bi-monthly (every two months) to ensure its reliability and adequacy and that such testing include the actuation of a different device during each successive test so that no individual device is used for two consecutive tests.

OSHA proposes in paragraph (d)(3) that power supplies be maintained at all times. OSHA is proposing that a back-up means of notifying employees of an emergency be provided during periods when the alarm system is inoperative.

OSHA proposes in paragraph (d)(4) that every emergency alarm system provided after July 1, 1980, be monitored so that a failure of the system would cause a positive signal to be transmitted to personnel indicating that there is a deficiency in the system.

OSHA proposes in paragraph (e) that all manual alarm stations be unobstructed, approved, conspicuous and readily accessible, and be located within 200 feet of employee workstations.

Section 1910.165—Fire brigades. The section for fire brigades is reserved in § 1910.164 of the present Subpart L standards. However, requirements for fire brigades are now proposed to be included in subpart L as a new § 1910.165. The decision to propose standards for fire brigades is a result of the following factors:

(1) Information collected by OSHA indicates that deaths and injuries of employees have occurred while fighting fires as members of fire brigades and related organizations; and

(2) Comments received support the concept that there should be requirements to ensure that employees who are members of fire brigades be trained and physically capable of performing required duties.

Therefore, OSHA is proposing a standard for fire brigades in § 1910.165. The present §§ 1910.165 and 1910.165a are proposed to be revoked because they only contain NFPA references.

OSHA is proposing in paragraph (a), to set forth the scope and application of this section. The requirements of the section would only apply to those fire brigades organized to protect workplaces and the employees therein; and, to those private or contract type fire departments which fall within the jurisdiction of OSHA.

OSHA has no direct jurisdiction over volunteer, local, or State government operated fire departments. Therefore, such departments would not be covered by this section. The proposed section also does not address the hazards of, nor does it apply to, forest fire fighting or airport "crash-rescue" type operations. The proposed requirements contained in § 1910.165 would not be appropriate because of the specialized nature of these types of fire fighting operations.

OSHA is proposing in paragraph (b), requirements for the organization of fire brigades.

In paragraph (v)(1) OSHA is proposing a requirement for the preparation of an organizational statement which would be the written policy of the employer pertaining to fire brigades. The statement would include a description of the function the brigade is to perform.

The organizational statement would be required to be kept at the workplace and available for inspection by employees, the Assistant Secretary of Labor for Occupational Safety and Health or designee. The statement would be intended to be a tool to aid employees in understanding their responsibilities and would help the compliance officer in determining if the level of training is consistent with the functions the brigade would be expected to perform.

In paragraph (b)(2) OSHA is proposing a requirement that brigade members be physically capable of performing the duties assigned to them in a safe manner.

Physical capability can be determined by such methods as preplacement physical examinations, physical agility tests, and periodic physical reexaminations using stress tests. The proposed standard would not require any specific type of examination, nor would it specify any frequency for screening; this would be decided by the medical professional in charge.

It would also specify that employees with known heart disease, epilepsy, or emphysema could not participate in fire brigade emergency activities unless permitted to do so by a certificate issued by a licensed physician.

OSHA is proposing training requirements for fire brigades in paragraph (c). The comments OSHA has received support the concept of the formation of fire brigades and that members should be properly trained to perform the duties they are expected to carry out during brigade activities.

Paragraph (c)(1) would require training to be commensurate with those functions that the fire brigade would perform. The intent of this requirement is to assure that a training program is developed for brigade members while at the same time providing enough flexibility in the requirement so that the training program could be tailored to meet the needs of the fire brigade.

In paragraph (c)(2) OSHA is proposing that training be conducted frequently enough to ensure that assigned duties and functions would be performed satisfactorily and in a safe manner so as not to endanger brigade members or other employees. OSHA also proposes that a training session be conducted for all brigade members at least annually.

OSHA is proposing in paragraph (c)(3) that training include hands-on training where brigade members operate the equipment which they are expected to use, and perform or simulate the operations they are expected to perform during emergency situations.

Regardless of the type of training program developed, it is imperative that brigade members know what to do in emergency situations and how to do it. Just as important, brigade members should know how it feels to operate fire equipment and what to expect from it. During training sessions, brigade members should actually perform those operations which may be assigned to them during emergency situations, such as discharging extinguishers and performing ladder or hose evolutions. Most of the comments OSHA has received concerning training support this concept.

OSHA is proposing in paragraph (c)(4), a requirement that brigade members be informed of special hazards in the workplace that could pose problems during firefighting. Since OSHA is mandated to protect the health and safety of the Nation's workers, OSHA believes this requirement is necessary to ensure that employees will be well informed of special hazards to which they may be exposed as members of a fire brigade.

In the appendix relating to this section, is contained recommended elements which should be incorporated into a fire brigade training program. The recommendations in the appendix should not be considered to contain all the necessary elements for a complete and comprehensive training program;

but they may be helpful as a guide in developing such a program.

OSHA is proposing in paragraph (d), a requirement that fire brigade equipment be maintained and periodically inspected to ensure safe operational condition of the equipment.

OSHA is proposing in paragraph (e), requirements for protective clothing which would apply only to fire brigade members who perform interior structural firefighting. OSHA has received comments suggesting that protective clothing standards be applicable to all types of firefighting. OSHA is aware of the hazards of other types of firefighting, but believes that interior structural firefighting poses a special type of hazardous situation faced by fire brigade members. Therefore, OSHA is limiting these proposed requirements to protective clothing worn during interior structural firefighting.

This proposed paragraph would not preclude giving supervisory personnel the discretion of allowing brigade members to remove certain protective clothing when fire conditions abate to the extent that mop-up or salvage operations are being performed. The intent of the proposed requirements for protective clothing is to ensure protection of brigade members who can expect to be inside of buildings and enclosed structures fighting fires beyond the incipient stage and exposed to extreme temperatures and toxic super-heated products of combustion.

The protective clothing to be covered by these proposed requirements would provide foot and leg protection, body protection, hand protection, and head, eye and face protection.

OSHA is proposing in paragraph (e)(1), three general requirements for protective clothing. The first proposed general requirement would allow a five year phase-in period for protective clothing used to meet this standard. Protective clothing purchased after July 1, 1980 would have to meet the proposed criteria. All protective clothing which would be worn while performing interior structural firefighting would have to meet the proposed criteria by July 1, 1985.

The second proposed general requirement would require that brigade members wear protective clothing while performing interior structural firefighting. OSHA has received comments suggesting that brigade members also wear protective clothing when responding to fire emergencies. OSHA would strongly recommend that such clothing be worn while on fire apparatus, responding to fire emergencies. Since there are many brigade members who respond on foot to a fire or to a predetermined location and then acquire their protective

equipment and gear, OSHA is only proposing a requirement that protective clothing be worn during interior structural firefighting.

The final proposed general requirement would specify the elements of the protective clothing ensemble which are necessary to meet the proposed standard.

OSHA is proposing three requirements for foot and leg protection in paragraph (e)(2). The first proposed requirement would identify two alternative methods for satisfying the foot and leg protection requirements of this section. Foot and leg protection can be achieved by: (1) Fully extended boots which protect the legs and meet the requirements of this section; or by, (2) protective shoes or boots and trousers which meet the requirements of this section.

The use of foot and leg protection, as well as fire-resistant coats, should be coordinated to ensure full body protection for the wearer. The proposed requirement recognizes the interdependence of protective clothing to cover one or more parts of the body. Therefore, the option is given so that brigade members can wear long fire-resistant coats in combination with fully extended boots; or, members can wear shorter fire-resistant coats in combination with protective trousers and protective shoes or shorter boots.

The second proposed requirement in paragraph (e)(2) for foot and leg protection would require protective footwear to meet § 1910.136 for Class 75 footwear. Section 1910.136 references ANSI Z41.1, (1967) "American National Standard for Men's Safety-Toe Footwear." This second proposed requirement in paragraph (e)(2) would also require protective footwear to be water-resistant for at least five inches above the heel and to be equipped with slip-resistant outer soles.

The final proposed requirement in paragraph (e)(2) specifies penetration-resistance of the sole of protective footwear. OSHA believes that employees performing firefighting operations need protection for the feet when stepping on nails or other sharp objects. It would state that when tested in accordance with "Military Specifications for Fireman's Boots," MIL-B-2885D (1973 and amendment 1975), protective footwear should provide protection against penetration of the midsole by a size 8D common nail when at least 300 pounds of static force is applied to the nail.

OSHA proposes two requirements for body protection in paragraph (e)(3). The first proposed requirement would allow body protection to be achieved by one of the following methods: (1) Wearing of a fire-resistant coat in combination with fully extended boots; or, (2) wearing of a fire-resistant

coat in combination with protective trousers. This proposed requirement is intended to coordinate the wearing of fire-resistant coats with foot and leg protection to ensure full body protection.

The second proposed requirement consists of criteria for fire-resistant coats and protective trousers. OSHA proposes to adopt the requirements of the NFPA standard for protective clothing for structural firefighting (NFPA No. 1971-1975) with the following variations in those requirements to provide flexibility in selection without sacrificing employee protection.

(a) The liner may be detachable but the shell would not be permitted to be worn without the liner while performing interior structural firefighting.

(b) The protected ventilation openings would be permitted to increase ventilation of trapped body heat.

(c) The tearing strength of the outer shell would be required to be a minimum of eight pounds.

(d) The criteria for flame-resistance of the outer shell surfaces after the removal of a test flame would be:

Maximum after-flame—2 seconds
Maximum after-glow—4 seconds
Average char-length—6 inches.

(e) The outer shell and lining would be permitted to char or discolor but would have to retain heat resistance and could not separate or melt when placed in a forced air laboratory oven at a temperature of 500°F (260°C.) for a period of five minutes.

The main reason OSHA is proposing to adopt certain requirements of the NFPA No. 1971 (1975) standard is to provide minimum criteria for fire-resistant coats and protective trousers. The NFPA 1971 standard is currently the recognized consensus standard covering the subject matter.

OSHA is proposing requirements for hand protection in paragraph (e)(4). The hand is one of the body parts most frequently injured during firefighting. Even while wearing gloves, fire fighters have sustained injuries to the hands (and wrists) from radiant and conductive thermal energy, as well as from cuts, abrasions, and punctures.

The first two proposed requirements for hand protection would establish performance criteria for protective gloves. The first requirement would state that hand protection consist of protective gloves or glove systems which allow dexterity of hand movement and sense of feel for objects.

The second requirement would state that the exterior material of protective gloves provide resistance against abrasion, puncture, and absorption of liquids.

The third proposed requirement for hand protection would state that gloves be fire-resistant. This proposed requirement would reference Federal

Test Method Standard No. 191-1971, "Textile Test Methods," and would state that the maximum after-flame be 2.0 seconds and the maximum char length be 4 inches.

The fourth proposed requirement in paragraph (e)(4) would state that thermal insulation of gloves be sufficient to prevent the temperature inside the gloves from exceeding 111°F (44°C) when the gloves are exposed to 932°F (500°C) for five seconds at 4 psi (28 kPa) pressure. OSHA proposes that the testing be done in accordance with the NIOSH publication, "The Development of Criteria for Firefighters' Gloves; Vol. II: Glove Criteria and Test Methods" (1976).

The final proposed requirement for hand protection would state that when the design of the fire-resistant coat does not otherwise provide protection for the wrists, protective gloves shall have wristlets of at least 4.0 inches (10.2 cm) in length to protect the wrist area when the arms are extended upward and outward from the body. Wristlets of 4 inches in length would be considered to be the minimum length necessary to protect the wrist area.

OSHA is proposing requirements for head, eye, and face protection in paragraph (e)(5).

The first proposed requirement in paragraph (e)(5) addresses head protection. OSHA proposes to adopt the requirements contained in the National Fire Prevention and Control Administration's (NFPCA) document, "Model Performance Criteria for Structural Firefighters' Helmets," (1977). OSHA believes that the criteria contained in ANSI Z89.1-1969 for Class D helmets are no longer satisfactory for providing proper protection of brigade members while performing interior structural firefighting.

OSHA believes that the NFPCA document contains all of the criteria necessary for proper head protection and that this criteria are the best which has been developed to date.

The NFPCA document is based on research conducted by the Institute for Applied Technology, National Bureau of Standards and it contains performance and testing criteria for: Impact attenuation; penetration resistance; chin strap/retention system; ear flaps; configuration; flame resistance; heat resistance; electrical insulation; and visibility and reflectivity. The ANSI Z89.1 standard does not adequately address these factors.

The last two proposed requirements in paragraph (e)(5) address eye and face protection because employees fighting fires are often exposed to falling and flying materials which could cause eye and face injuries. In order to guard against such injuries, OSHA is proposing that protective eye and face

devices complying with §1910.133 be used by brigade members when performing operations where the hazards of flying or falling materials are present and which may cause eye and face injuries. Many head protective devices include face shields as accessories. Additionally, full-facepieces of breathing apparatus meeting the requirements of §1910.134 and paragraph (f) of this proposed section would also be acceptable as meeting the proposed requirements for eye and face protection.

OSHA is proposing requirements for respiratory protective devices in paragraph (f).

Paragraph (f)(1) would contain general requirements for all respiratory protection devices used by fire brigade members. Paragraph (f)(2) would contain requirements for positive-pressure breathing apparatus.

In the first general requirement, respiratory protective devices would have to meet the requirements of §1910.134 and this paragraph. OSHA believes that §1910.134 provides an effective framework for a respiratory program; however, some additional criteria are needed in order to provide greater protection for fire brigade members because of the severe hazards present in the work environment.

The second proposed general requirement would state that approved self-contained breathing apparatus with full-facepiece should be worn by brigade members while working inside buildings or confined spaces where there is dense smoke, an oxygen deficiency or temperature extremes. The proposed requirement would also state that such apparatus be worn during emergency situations involving toxic substances. OSHA believes it is necessary to require the wearing of self-contained breathing apparatus with a full-facepiece in those instances when fire brigade members are exposed to smoke, elevated temperature extremes, oxygen deficiencies, or toxic substances, because other types of breathing apparatus would not provide adequate protection.

The third proposed general requirement would allow breathing apparatus to be equipped with a "buddy-breathing" device or a quick disconnect type valve or both as long as such accessories do not cause damage to the apparatus, restrict the air flow of the apparatus, or obstruct the normal operation of the apparatus.

The first of these accessories, the buddy-breathing device, is a device where a second person can share the same air supply as that of the wearer of the apparatus. Its use is intended only during emergency escape situations. The device precludes the need to pass the facepiece between two brigade members.

There have been instances reported where a fire-fighter's air supply has been depleted because of being pinned or trapped, or as a result of a malfunction of the apparatus. The availability of a second air supply would assist an endangered firefighter.

A safer and improved procedure to use in such a situation is to have a buddy-breathing device incorporated into the breathing units that would allow for two facepiece hose connections. With this type of device, both facepieces are connected into a common air supply and both firefighters would be benefitted by the available air.

The second accessory, a quick disconnect valve, is a device which starts the flow of air by insertion of the facepiece hose into the regulator of a self-contained breathing apparatus, and stops the flow of air by disconnection of the hose from the regulator. OSHA proposes to permit this type of device because it would assist in the use of positive-pressure type breathing apparatus and would aid in the conservation of the air supply.

The fourth proposed general requirement permits the interchangeability of certified air bottles. OSHA believes the interchangeability of certified air bottles is necessary because the breathing apparatus used by a fire department (providing aid to a fire brigade) and the breathing apparatus of the fire brigade may be made by different manufacturers. There may also be breathing apparatus within the brigade or fire department itself which is made by different manufacturers.

The proposed requirement would state that approved self-contained compressed air breathing apparatus be compatible when used with other approved cylinders of the same size and pressure rating and may be interchanged. The proposed requirement would also state that all compressed air cylinders used with self-contained breathing apparatus shall meet DOT and NIOSH criteria.

The fifth proposed general requirement would state that self-contained breathing apparatus shall have a minimum service life rating of 30 minutes in accordance with the methods and requirements of MSHA and NIOSH. It is generally accepted that breathing apparatus which is rated at 30 minutes, in actuality, lasts only 15-18 minutes, mainly because of the physical activity of firefighters. In light of this, OSHA believes that the 30 minute-rated breathing apparatus provides only the minimum amount of time to be effective in a fire emergency situation. Consequently, self-contained breathing apparatus with a NIOSH minimum service life rating of 30 minutes is specified. Situations which may require longer service life include

entry and escape from cellars, basements, ships, and tunnels.

The sixth proposed general requirement would state that each breathing apparatus be fully recharged and cleaned after each use. Self-contained breathing apparatus would also be required to be stored in such a manner that it would be maintained in a clean and operable condition.

The proposed requirement would not specify any particular method or location for storing the apparatus. Instead, it would only require that the apparatus be stored in a manner that will result in the apparatus being maintained in a clean and operable condition. This would provide some flexibility in the storage method for the self-contained breathing apparatus.

The seventh proposed general requirement concerns an audible alarm which will automatically sound when the remaining service life of the apparatus is reduced to within a range of 20-25 percent of its rated service time. The purpose of this requirement is to provide an early notification mechanism to the wearer that the air supply has been reduced to such a level that escape should be started.

OSHA is proposing in paragraph (f)(2), the following requirements for positive-pressure breathing apparatus.

The first requirement would state that self-contained breathing apparatus purchased after July 1, 1980, be of the pressure-demand or other positive-pressure type when such apparatus is worn by brigade members while performing interior structural firefighting operations. Effective July 1, 1983, this requirement would apply to all self-contained breathing apparatus when used while performing interior structural firefighting. This three year delay would allow for the gradual introduction of positive-pressure type breathing apparatus and would permit an orderly transition to positive pressure respirator.

When a brigade member performs interior structural fire fighting, he is being exposed to unknown concentrations of contaminants. Brigade members do not normally know what contaminants they are encountering, let alone the exact concentrations of the materials which may be present. In light of this uncertainty, brigade members must be provided with the type of respirator which affords the best protection against the unknown environments they may be entering. This is the reason that OSHA believes that positive-pressure breathing apparatus must be used when performing interior structural fire fighting.

The second proposed requirement permits the use of a combination type self-contained breathing apparatus if the apparatus can be switched from a

demand to a positive-pressure mode. However, such apparatus would still be required to be in the positive-pressure mode when brigade members are performing interior structural fire fighting.

The allowance of combination-type respirators to meet the requirements of this proposed section would provide some flexibility in the use of the apparatus. For instance, it would be permissible to have apparatus in the demand mode when performing firefighting operations other than those defined as interior structural firefighting. Additionally, it would be permissible to be in the demand mode when responding to the fire location or ascending stairs to the fire floor before actual interior structural firefighting operations begin.

The last proposed requirement would state that, effective July 1, 1985, new positive-pressure breathing apparatus, including full-facepieces, shall be capable of performing to temperatures of -20°F (-40°C). This property is necessary because of the possible conditions that would be encountered during firefighting activities.

At present, NIOSH does not have test criteria for elevated temperatures. However, OSHA believes it is imperative that appropriate test criteria be established to ensure serviceability of the apparatus during interior structural firefighting operations; and, OSHA believes that technology and resources are available such that this proposed requirement could be easily implemented by the July 1, 1985 effective date of this standard.

IV. REFERENCES

1. "A Study of Facepiece Leakage of Self-Contained Breathing Apparatus by DOP Man Test—Progress Report—July 1, 1971-February 29, 1972"; Los Alamos Scientific Laboratory; Los Alamos, NM.
2. ANSI Z88.5-1973, "Practices for Respiratory Protection for the Fire Service"; American National Standards Institute; New York, NY.
3. "Design Specifications for Respiratory Breathing Devices for Firefighters"; National Institute for Occupational Safety and Health; Cincinnati, Ohio. 1975.
4. "A Report on the Performance of Firefighters' Helmets"; William I. Cook; NIOSH; Morgantown, WV. 1976.
5. ANSI Z90.1; "Specification for Protective Headgear for Vehicular Users"; American National Standards Institute; New York, NY. 1971.
6. ANSI Z41.1; "American National Standard for Men's Safety-Toe Footwear"; American National Standards Institute; New York, NY. 1967.
7. NBSIR 75-702; "Design Criteria for Firefighters' Turnout Coats." Prepared for NFPCA by National Bureau of Standards; Washington, D.C. 1975.
8. Hyatt, Edwin C.; "Respirator Protection Factors"; Los Alamos Scientific Laboratory; Los Alamos, NM. 1976.
9. "The Development of Criteria for Firefighters' Gloves Volume I: Glove Requirements and Volume II: Glove Criteria and Test Methods"; NIOSH; Morgantown, WV. 1976.
10. "Model Performance Criteria for Structural Firefighters' Helmets"; NFPCA; Washington, D.C. August 1977.
11. NFPA-27; "Private Fire Brigades"; National Fire Protection Association; Boston, MA. 1975.
12. NFPA-1971; "Protective Clothing for Structural Fire Fighting"; National Fire Protection Association; Boston, MA. 1975.
13. FEDERAL REGISTER Notice; April 9, 1974 (39 FR 12864).
14. 30 CFR Part 11; "Respiratory Protective Devices; Tests for Permissibility; Fees." 1972.
15. Federal Test Method Standard; "Textile Test Methods." 1968.
16. "A Comprehensive Study of Fire Fighter Injuries and Injury Reporting Systems"; International Association of Fire Fighters; Washington, D.C. October 1977.
17. NFPA-1001; "Initial Fire Attack"; National Fire Protection Association; Boston, MA. 1966.
18. NFPA-4; "Organization For Fire Services"; National Fire Protection Association; Boston, MA. 1971.
19. NFPA-6; "Organization of Industrial Fire Loss Prevention"; National Fire Protection Association; Boston, MA. 1974.
20. NFPA-9; "Training Reports and Records"; National Fire Protection Association; Boston, MA. 1970.
21. ANSI Z89.1; "Safety Requirements of Industrial Head Protection"; American National Standards Institute; New York, NY. 1969.
22. *Washington Star*; "Additional Worries for Fairfax Firemen: Helmets That Melt." Washington, D.C. Oct. 25, 1977.
23. Seymour, Thomas H.; "A Study of Personal Protective Clothing Standards for Fire Fighters"; Fire Protection Engineering Curriculum; University of Maryland. 1972.
24. Military Specification; "Boots, Firemen's"; MIL-B-2885D. May 1973.
25. "How Safe Are Your Turnouts?"; *Firehouse*. October 1977.
26. FEDERAL REGISTER; "Respirator Testing and Approval." Friday, October 28, 1977.
27. FEDERAL REGISTER; "Safety Standards Revision Procedures Walking-Working Surfaces. Anhydrous Ammonia, Fire Protection, Request for Information; Proposal Withdrawal"; Friday, April 23, 1976.
28. Clougherty, Dr. Edward V.; "Boston's Experience with Protective Clothing"; *Firemen*. October, 1978.
29. Held, Bruce J.; "History of Respiratory Protective Devices in the U.S."; Lawrence Livermore Laboratory. August 1977.
30. Held and Richards; "Research and Development Needs in Firefighters' Breathing Protection"; Lawrence Livermore Laboratory. February 1977.
31. "Fire Safety Aspects of Polymeric Materials; Volume 1—Materials; State of the Art." A Report by National Materials Advisory Board, National Academy of Sciences. 1977.
32. OSHA Program Directive #300-9; "OSHA Standard Method for Determination of Respiratory Protective Program Acceptability." June 1977.
33. "Proposed Sample Standards for Fire Fighters Protective Clothing and Equipment"; International Association of Fire Fighters; Washington, D.C.

34. "Marshals for Safety"; *Navy Lifeline*. September/October 1977.
35. "Organization and Training of an Industrial Volunteer Fire Brigade"; Vought Corporation Systems Division; Dallas, TX.
36. "Workbook for Initiating the IAFC/IAFF Fire Fighter Apprenticeship Program"; IAFC/IAFF Joint Apprenticeship Program for Fire Fighters; Washington, D.C.
37. "Changes Ahead for Safety Footwear?"; *National Safety News*. July 1975.
38. "Improved Firefighters' Crash-Rescue Boots (Feasibility Study)"; Technical Report No. 120. Navy Clothing and Textile Research Facility; Natick, MA. 1976.
39. "A Preliminary Investigation of the Performance of Men's Safety-Tone Footwear"; Cook and Groce, NIOSH; Morgantown, WV. 1975.
40. "Aluminized Firemen's (Fire Proximity) Handwear: A Comparative Study of Dexterity Characteristics"; Technical Report No. 121. Navy Clothing and Textile Research Facility; Natick, MA. 1976.
41. "Firefighter's Glove Hazard"; *Navy Lifeline*. July/August 1977.
42. *The Safety Journal*; "New Gloves." June/July 1977.
43. *Fire Engineering*; "Injuries Show What Protection Improved Clothing Should Offer." 1972.
44. "New Hazards for Firefighters"; *Job Safety and Health*. U.S. Department of Labor. February 1975.
45. Utech et al.; "The Firefighter's Turn-out Coat: A Design Analysis"; *Journal of Safety Research*. March 1974.
46. Krasny and Peacock; "Comments on Flammability Assessment of Apparel Fabrics"; *Textile Chemist and Colorist*. April 1977.
47. "A Report of the State-of-the-Art of Protective Clothing and Equipment for Municipal Firefighters"; National Fire Safety and Research Office, National Fire Prevention and Control Administration. 1977.
48. "Measurement of Thermal Performance of Clothing Used by Firefighters With Some Interpretations"; Geoscience LTD, for United Firefighters of Los Angeles. 1977.
49. "Protective Clothing and Equipment Survey"; International Association of Fire Fighters; Washington, D.C. 1977.
50. "Lightweight Aluminized Fabrics and Insulation-Liner Materials for Proximity Firefighters' Garments"; Technical Report No. 114; Navy Clothing and Textile Research Unit; Natick, MA. 1975.
51. "Non-Reflective, Wettable, Fibrous, Fabric Assemblies for Firefighters' Clothing"; Technical Report No. 123. Navy Clothing and Textile Research Facility; Natick, MA. 1977.
52. "NBS Develops Helmet Standard"; *Fire Engineering*. July 1976.
53. "What's Ahead in Hard Hats?"; *National Safety News*. April 1975.
54. "Standards Not Adequate for Fire Fighter's Helmet"; *Fire Engineering*.
55. "Development of Criteria for Industrial and Firefighters' Head Protective Devices"; NIOSH; Cincinnati, OH. 1975.
56. "Head Protection: A Top Priority"; *Fire Command*. April 1976.
57. ANSI Z89.2; "Safety Requirements for Industrial Protective Helmets for Electrical Workers, Class B"; American National Standards Institute; New York, NY. 1971.
58. "Report on Tests on Class B Industrial Helmets"; NIOSH; Morgantown, WV. 1975.
59. McDough, Joseph M.; "Pressure Demand Breathing Apparatus for Firefighters." November 1, 1976.
60. McDonagh, Joseph M.; "Warning, Self-Contained Breathing Apparatus Users." *Maryland Fire and Rescue Bulletin*. 1977.
61. ANSI Z88.2; "Practices for Respiratory Protection"; American National Standards Institute; New York, NY. 1969.
62. ANSI Z86.1; "Commodity Specification Fire Air"; American National Standards Institute; New York, NY. 1973.
63. "Better Testing. Use of Safety Pressure SCBA's May Save Lives"; *Occupational Health and Safety*. September/October 1977.
64. "Breathing Apparatus Regulations Challenged"; *Fire Command*. January 1977.
65. Utech, H. P.; "Eating Smoke—the Dispensable Diet"; *The Fire Independent*. 1975.
66. Utech, H. P.; "Facing Up to Leakage"; *The Fire Independent*. 1975.
67. Utech, H. P.; "Overcoming Facepiece Leakage"; *The Fire Independent*. 1975.
68. Radford and Levine; "Occupational Exposure to Carbon Monoxide in Baltimore Firefighters"; Johns Hopkins University; Baltimore, Maryland; *Journal of Occupational Medicine*. September 1976.
69. Peabody, Homer D.; "Pulmonary Function and the Fire Fighter"; *The Journal of Combustion Toxicology*. February 1977.
70. Sidor and Peters; "Fire Fighting and Pulmonary Function"; *American Review of Respiratory Disease*. Vol. 109, 1974.
71. "Firefighters' Breathing System Study"; Federal Systems Division, International Business Machines Corporation. 1972.
72. "A Guide to Industrial Respiratory Protection"; NIOSH; Cincinnati, OH. 1976.
73. "Master Blueprint for Hand and Body Protection"; *Occupational Hazards*. Vol. 35; March 1973.
74. "Good Health Through Physical Fitness"; Los Angeles City Fire Department. 1971.
75. Dotson, et. al.; University of Maryland. "Development of a Job Related Physical Performance Examination for Firefighters"; A Summary Report to the National Fire Prevention and Control Administration. March 1977.
76. California Proposed Occupational Safety and Health Standards; "Personal Protective Clothing and Equipment for Firefighters." 1977.
77. "Firemen's Safety Standards Backed"; *Los Angeles Times*. August 19, 1977.
78. Barnard and Duncan; "Heart Rate and ECG Responses of Fire Fighters"; *Journal of Occupational Medicine*. April 1975.
79. Barnard, et al.; "Near-Maximal ECG Stress Testing, and Coronary Artery Disease Risk Factor Analysis in Los Angeles City Fire Fighters"; *Journal of Occupational Medicine*. November 1975.
80. Barnard, et al.; "Ischemic Heart Disease in Fire Fighters with Normal Coronary Arteries"; *Journal of Occupational Medicine*. December 1976.
81. "Fire Technology Broadened in Three Areas"; *National Safety News*. June 1975.
82. 29 CFR Part 1910; "General Industry Standards"; Occupational Safety and Health Administration. 1972.
83. Washington State; "Proposed Safety Standards for Fire Fighters." August 1977.
84. Batzer, M. M.; "Increased On-The-Job Fire Training"; *National Safety Congress*. 1961.
85. "Fire Protective Clothing for the Navy"; *Firemen*. January 1969.
86. "Fire Brigades"; National Safety Council. 1966.
87. Crapnell, Stephen G.; "Chevrolet's One-Two Punch: Crack Fire Brigade and Comprehensive Fire Protection Engineering"; *Occupational Hazards*. November 1977.
88. Davis, Paul O.; "Physical Fitness and the Firefighter"; *Fire Command*. April 1974.
89. Davis, Paul O. and D. L. Santa Maria; "Testing Physical Fitness"; *Fire Command*. 1975.
90. "Project Monoxide—A Medical Study of an Occupational Hazard of Fire Fighters"; International Association of Fire Fighters; Washington, D.C.
91. Sammons and Coleman; "Firefighter's Occupational Exposure to Carbon Monoxide"; *Journal of Occupational Medicine*. Volume 16, No. 8, 1974.
92. American National Standards Institute; "Acceptable Concentrations of Carbon Tetrachloride"; ANSI; New York, NY 10018. 1967.
93. Bukowski, R.; Custer, R.; and Bright, R.; "Fire Alarm and Communication Systems, NBS Tech Note 964"; National Bureau of Standards; Washington, D.C. April 1978.
94. Custer, Richard; "Detector Actuated Automatic Sprinkler Systems—A Preliminary Evaluation, NBS Tech Note 836"; National Bureau of Standards; Washington, D.C. July 1974.
95. Custer, Richard and Wahle, Klaus; "Distribution of Water Through a Vertical Plane From Automatic Sprinkler Heads, NBSIR 75-920"; National Bureau of Standards; Washington, D.C. December 1975.
96. Federal Fire Council; "Portable Fire Extinguisher Studies"; Federal Fire Council; Washington, D.C. October 1965.
97. Federal Fire Council; "Case Histories of Deaths and Injuries from Carbon Tetrachloride Fire Extinguishers"; Federal Fire Council; Washington, D.C. April 1967.
98. Federal Fire Council; "Hazard of Carbon Tetrachloride Fire Extinguishers—Recommended Practices Number 3"; Federal Fire Council; Washington, D.C. January 1967.
99. Ford, Charles; "An Overview of Halon 1301 Systems"; American Chemical Society. 1975.
100. Industrial Commission of Ohio, Division of Safety and Hygiene; "Abolish Carbon Tet Fire Extinguishers"; *Monitor*; October 1970; pp 4-5; Industrial Commission of Ohio.
101. Keating, J. P. and Loftus, E. F.; "Vocal Emergency Alarms in Hospitals and Nursing Facilities: Practice and Potential NBS-GCR-77-102"; National Bureau of Standards; Washington, D.C. July 1977.
102. "L. A. Crash Truck with AFFF Halts Chemical Storage Fire"; *Fire Engineering*; October 1972, pp 40-41.
103. Manufacturing Chemists' Association; "Chemical Safety Data Sheet SD-3, Carbon Tetrachloride"; Manufacturing Chemists' Association, Inc.; Washington, D.C. 1963.
104. Maxfield, Mary; "Toxicity of Bromotrifluoromethane, Haskell Laboratory Report No. 577-74, Medical Research Project No. 1803-1"; Haskell Laboratory for Toxicology and Industrial Medicine; E. I. duPont de Nemours and Co.; Wilmington, Del. August 1974.
105. National Association of Fire Equipment Distributors; "Fire Extinguishers Can

Be Dangerous If . . .": NAFED; Chicago, IL; 60601, 1976.

106. "NAFED'S Extinguisher-Use Study Results Stress High Protection Effectiveness at OSHA Hearings"; *Firewatch*; Vol. 13, No. 3; 1976; National Association of Fire Equipment Distributors; Chicago, IL.

107. National Association of Fire Equipment Distributors; "Discontinued Fire Extinguishers, How Unsafe? How Ineffective?"; NAFED; Chicago, IL, 1974.

108. National Fire Protection Association; *Fire Protection Handbook*; 13th and 14th Editions; National Fire Protection Association; Boston, MA 02201.

109. National Fire Protection Association; *National Fire Codes*, Vols. 1 and 2; National Fire Protection Association; Boston, MA 02201, 1974, 1975, 1976, 1977, and 1978.

110. National Institute for Occupational Safety and Health; "Criteria for a Recommended Standard . . . Occupational Exposure to Phosgene"; U.S. Department of Health, Education and Welfare; Washington, D.C. 1976.

111. National Institute for Occupational Safety and Health; "Criteria Recommended Standard . . . Occupational Exposure to Carbon Tetrachloride"; U.S. Department of Health, Education and Welfare; Washington, D.C. 1975.

112. National Institute for Occupational Safety and Health; "Criteria for a Recommended Standard . . . Occupational Exposure to Carbon Dioxide"; U.S. Department of Health, Education and Welfare; Washington, D.C. 1976.

113. National Research Council; "An Appraisal of Halogenated Fire Extinguishing Agents"; Proceedings of a Symposium held April 11-12, 1972; National Academy of Sciences; Washington, D.C. 1972.

114. National Safety Council; *Accident Prevention Manual for Industrial Operations*; 7th Edition; National Safety Council; Chicago, IL, 1974.

115. Stahl, Fred I. and Archea, John; "An Assessment of the Technical Literature of Emergency Egress from Buildings, NBSIR 77-1313"; National Bureau of Standards, Washington, D.C. October 1977.

116. U.S. Air Force; "Extinguishment of Alkali Metal Fires"; Technical Documentary Report No. APL TDR 64114, October 1974; Air Force Aero Propulsion Laboratories, Wright-Patterson Air Force Base, OH.

V. REGULATORY ASSESSMENT STATEMENT

In accordance with Executive Order No. 12044 (43 FR 12661, March 24, 1978), OSHA has assessed the potential economic impact of this proposal. Based on the economic identification criteria proposed by the Department of Labor (43 FR 22915, May 26, 1978), OSHA has concluded that the subject matter of this proposal is not a "major" action which would necessitate further economic impact evaluation and the preparation of a Regulatory Analysis.

JRB Associates, Inc., has prepared for OSHA an economic assessment entitled "Economic Impact Assessment of 29 CFR Part 1910 Subpart L—Fire Protection." The study includes assessment of the technological feasibility of compliance as well as an estimate of compliance costs. The effects on other

variables, such as employment, productivity, and market structure, are considered.

According to the study, compliance costs are not expected to exceed \$20 million for any of the years 1979 to 1983. In 1984, compliance costs are expected to peak at \$21 million, but after 1984, these costs will decline considerably. The study concludes that at present time, compliance with the proposed standard is both economically and technically feasible. Additionally, the proposed modifications to Subpart L are not expected to have any other economic impact that might be considered major. Due to training requirements, the proposed standard could possibly result in a marginal increase in employment. This effect will not be significant when distributed across the entire economy. No significant market structure effects are projected due to regulatory restraints proposed on certain products. The study therefore concludes that, based on data available at the time of analysis, the proposed changes will not have a major economic impact as defined by Executive Order 12044 and criteria proposed by the Department of Labor pursuant to this order.

The economic impact assessment has identified several benefits that will be realized as a result of promulgation of the proposed changes to Subpart L. Some changes are intended to reduce accidents; others give the employer added flexibility. For example, the proposed regulation will prohibit the use of carbon tetrachloride and chlorobromomethane fire extinguishers in OSHA regulated workplaces. This will prevent injuries related to the discharge of toxic substances from fire extinguishers. The proposed regulation also requires the replacement of Soda-Acid and inverting foam extinguishers from OSHA regulated workplaces. Thus, the tendency of these extinguishers to rupture in testing or while in use will be prevented from causing injuries in OSHA regulated workplaces. The initial replacement cost of these extinguishers will be offset by long-run savings in reduced maintenance costs of the new extinguishers and scrap value of the old ones.

The proposed regulation provides for training and equipment for worker protection for those employees who are assigned as fire brigade members to fight interior structural fires. This is expected to reduce the number of injuries to employees involved in fire-fighting.

The proposed regulation includes several relaxations that provide added flexibility and possible additional cost savings. These include: The exemption from portable fire extinguisher requirements for some employers; and

exemptions for sprinkler systems, other fixed systems, employee alarm systems and fire detection systems not installed to meet other OSHA regulations.

Although it is not possible to compare the estimated cost of compliance to quantifiable dollar benefits, it is possible to compare the estimated cost of compliance to the cost of fire losses in OSHA regulated workplaces. The National Association of Fire Equipment Distributors (NAFED) estimates 87 percent of fire incidents that workers extinguish are not reported to public fire departments. For the fires that are reported, the National Fire Protection Association (NFPA) estimates U.S. structure fires and property loss by property use. Using NFPA statistics for 1977, it is derived that \$2.242 billion in property losses were incurred by OSHA regulated workplaces. Estimated compliance costs for the proposed regulations are less than one percent of the 1977 estimated property loss as a result of structure fires. In addition to reducing injuries associated with firefighting, the proposed regulation will also have a positive effect in the control of fires by increasing the reliability of fire extinguishers and providing for fire brigades that are better equipped and trained. If a one percent improvement in total fire losses can be realized, the estimated cost of the proposed regulation is completely offset.

OSHA certifies that this proposal is not "major" under E.O. 12044 and the proposed Secretary's guidelines (43 FR 22915).

The assessment is available for inspection and copying at the OSHA Technical Data Center, Room S6212, Third Street and Constitution Avenue, NW., Washington, D.C. 20210. OSHA invites comments concerning the conclusions reached in the economic impact assessment.

VI. PUBLIC PARTICIPATION

Interested persons are invited to submit written data, views and arguments with respect to this proposal. These comments must be postmarked on or before March 2, 1979, and submitted in quadruplicate to the Docket Officer, Docket S-004, Room S6212, U.S. Department of Labor, Washington, D.C. 20210. Written submissions must clearly identify the specific provisions of the proposal which are addressed and the position taken with respect to each issue.

The data, views and arguments that are submitted will be available for public inspection and copying at the above address. All timely submissions received will be made a part of the record of this proceeding.

Additionally, interested persons may file objections to the proposal and re-

quest an informal hearing with thereto. The objections and hearing requests should be filed in accordance with the following conditions:

1. The objections must include the name and address of the objector;
2. The objections must be postmarked on or before March 16, 1979;
3. The objections must specify with particularity the provisions of the proposed rule to which objection is taken and must state the grounds therefor;
4. Each objection must be separately stated and numbered; and
5. The objections must be accompanied by a detailed summary of the evidence proposed to be adduced at the requested hearing.

VI. AUTHORITY

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, Third Street and Constitution Avenue, N.W., Washington, D.C. 20210.

Accordingly, under sections 4(b)(2), 6(b), and 8(c) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 1599; 29 U.S.C. 653, 655, 657), Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR Part 1911, it is proposed to amend §§ 1910.35, 1910.37, 1910.107, 1910.108, 1910.109 of Title 29, Code of Federal Regulations; to add a new § 1910.38 and to revise Subpart L.

Signed at Washington, D.C. this 15th day of December 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

1. Section 1910.35 would be amended by adding two new paragraphs to read as follows:

§ 1910.35 Definitions.

(i) "Emergency action plan" means a plan for a workplace describing what the employee life safety hazards are and what actions the employer and employees must take in a life or injury threatening emergency. These actions may include employee escape, fire-fighting, notifying other employees or firefighting personnel of the emergency, or performing rescue or medical first aid duties.

(j) "Emergency escape" means the route through and from the workplace that employees would follow in the event they are required to evacuate the workplace or seek a designated refuge area. It may include the normal means of egress from the workplace as well as an unsupervised emergency

exit or an external wall opening such as a window.

2. Paragraph (n) of § 1910.37 would be amended to read as follows:

§ 1910.37 Means of egress, general.

(n) *Fire alarm signaling systems.* Employers shall assure that fire alarm signaling systems be maintained and tested in accordance with the requirements of § 1910.164a.

3. The heading for the existing § 1910.38 would be deleted and a new § 1910.38 would be added to read as follows:

§ 1910.38 Employee emergency plans.

(a) *Emergency action plan.*—(1) *Scope and application.* This paragraph applies to all emergency action plans required by a particular OSHA standard. The emergency action plan shall consist of and address all designated actions employees must take to ensure employee safety from fire and other emergencies.

(2) *Elements.* The following elements must be addressed in the plan:

(i) Emergency escape procedures and assignments;

(ii) Procedures to be taken by employees who remain to operate critical plant operations when the emergency alarm is first given to them before they evacuate;

(iii) Actions to account for all employees after emergency evacuation has been completed;

(iv) Rescue and medical first aid duties and those who are to perform them;

(v) The preferred means of reporting fires or emergencies and an acceptable back-up method or methods of notification;

(vi) The emergency duties of all employees when the alarm is given; and

(vii) Names of persons who can be contacted for further information or explanation of duties under the plan.

(3) *Alarm system.* The employer shall establish an employee alarm system which will comply with 29 CFR 1910.164a.

(4) *Evacuation.* The employer shall designate in the emergency action plan whether immediate and total evacuation or delayed and partial evacuation is planned.

(5) *Training.* (i) The employer shall designate and train a sufficient number of persons to assist in the safe and orderly emergency evacuation of employees.

(ii) The employer shall review the initial plan with all employees having

responsibilities under the plan and shall repeat the review whenever the plan is changed.

(iii) The employer shall give a copy of the plan to each employee upon initial employment and shall post it in the workplace for review. For those employers with 10 or fewer employees the plan may be conveyed orally to employees in lieu of posting.

(iv) The employer shall review the plan with an employee when that employee's job duties change to the extent that new emergency duties result.

(b) *Fire prevention plan.*—(1) *Scope and application.* This paragraph applies to all fire prevention plans required by a particular OSHA standard.

(2) *Elements.* The following elements shall be contained in the fire prevention plan:

(i) A list of the major workplace potential fire hazards, potential ignition sources and the type of fire protection equipment or systems which can control a fire involving them.

(ii) The preferred method of contacting the plant fire brigade or the public fire department with an acceptable back-up method or list of methods of notification.

(iii) Designated personnel responsible for maintenance of equipment and systems installed to prevent ignitions or fires.

(iv) Designated personnel for control of fuel source hazards.

(3) *Housekeeping.* The employer shall keep workplaces free of accumulations of flammable and combustible waste materials and residues which can contribute to a fire emergency.

(4) *Training.* (i) The employer shall train employees involved in the fire prevention plan in the recognition of potential fire hazard situations and the methods to correct them. Employees shall be apprised of the fire hazards of the materials and processes to which they are exposed.

(ii) The employer shall review the plan with all employees playing a role in its implementation.

(iii) The employer shall give a copy of the plan to each employee upon initial employment and shall maintain copies of the plan and shall post it in the workplace for review. For those employers with 10 or fewer employees the plan may be conveyed orally.

(5) *Maintenance.* The employer shall regularly and properly maintain equipment and systems installed to prevent ignitions or fires according to established procedures.

4. Paragraph (f)(1) of § 1910.107 would be amended to read as follows:

§ 1910.107 Spray finishing using flammable and combustible materials.

(f) *Protection.*—(1) *Conformance.* In sprinklered buildings, the automatic sprinkler system in rooms containing spray finishing operations shall conform to the requirements of 29 CFR 1910.159. In unsprinklered buildings where sprinklers are installed only to protect spraying areas, the installation shall conform with such standards insofar as they may be applicable. Sprinkler heads shall be located to effect water distribution throughout the entire booth.

5. Paragraph (g) of § 1910.108 would be amended to read as follows:

§ 1910.108 Dip tanks containing flammable or combustible liquids.

(g) *Extinguishment.*—(1) *Extinguishers.* Areas in the vicinity of dip tanks shall be provided with manual fire extinguishers suitable for flammable and combustible liquid fires, conforming to 29 CFR 1910.157.

(2) *Automatic water spray extinguishing systems.* Such systems shall conform to 29 CFR 1910.163 and shall be arranged to protect tanks, drainboards, and stock over drainboards.

(3) *Automatic foam extinguishing systems.* Automatic foam extinguishing systems shall conform to 29 CFR 1910.163 and; * * *

(4) *Automatic carbon dioxide systems.* Automatic carbon dioxide systems shall conform to 29 CFR 1910.162 and shall be arranged to protect both dip tanks and drainboards and unless stock over drainboards is otherwise protected with automatic extinguishing facilities, shall also be arranged to protect such stock.

(5) *Dry chemical extinguishing systems.* Dry chemical extinguishing systems shall conform to 29 CFR 1910.161 and shall be arranged to protect both dip tanks and drainboards, and unless stock over drainboards is otherwise protected with automatic extinguishing facilities, shall also be arranged to protect such stock.

6. Paragraph (i)(7) of § 1910.109 would be amended to read as follows:

§ 1910.109 Explosives and blasting Agents.

(i) *Storage of ammonium nitrate.* * * *

(7) *Fire protection.* (i) Not more than 2,500 tons of bagged ammonium

nitrate shall be stored in a building or structure not equipped with an automatic sprinkler system. Sprinkler systems shall be of the approved type and installed in accordance with 29 CFR 1910.159.

(ii)(a) Suitable fire control devices such as small hose or portable fire extinguishers shall be provided throughout the warehouse and in the loading and unloading areas. Suitable fire control devices shall comply with the requirements of §§ 1910.157 and 1910.158.

7. Section 1910.156 would be revised to read as follows:

§ 1910.156 Scope, application and definitions applicable to this subpart.

(a) *Scope.* This subpart covers all portable and fixed fire suppression equipment installed to meet the fire protection requirements of 29 CFR Part 1910.

(b) *Application.* This subpart applies to all industries except the maritime industry, construction, and agriculture industries which are covered by separate OSHA standards.

(c) *Definitions applicable to this subpart.* (1) "After-flame" means the time a test specimen continues to flame after the flame source has been removed.

(2) "Aqueous film forming foam (AFFF)" means a fluorinated surfactant with a foam stabilizer which is diluted with water to act as a barrier to exclude air and to develop an aqueous film on the fuel surface which is capable of suppressing the generation of fuel vapors.

(3) "Approved" means acceptable to the Assistant Secretary of Labor for Occupational Safety and Health under the following criteria:

(i) If it is accepted, or certified, or listed, or labeled or otherwise determined to be safe by a nationally recognized testing laboratory, such as, but not limited to, Underwriters' Laboratories, Inc. and Factory Mutual Engineering Corporation; or

(ii) With respect to an installation or equipment of a kind which no nationally recognized testing laboratory accepts, certifies, lists, labels, or determines to be safe, if it is inspected or tested by another Federal agency and found in compliance with the provisions of the applicable National Fire Protection Association Fire Code; or

(iii) With respect to custom-made equipment or related installations which are designed, fabricated for, and intended for use by its manufacturer on the basis of test data which the employer keeps and makes available for inspection to the Assistant Secretary and his authorized representative.

(iv) For the purposes of paragraph (c) (3) of this section:

(a) Equipment is listed if it is of a kind mentioned in a list which is published by a nationally recognized testing laboratory which makes periodic inspection of the production of such equipment and which states such equipment meets national recognized standards or has been tested and found safe for use in a specified manner;

(b) Equipment is labeled if there is attached to it a label, symbol, or other identifying mark of a nationally recognized testing laboratory which makes periodic inspections of the production of such equipment, and whose labeling indicates compliance with nationally recognized standards or tests to determine safe use in a specified manner;

(c) Equipment is accepted if it has been inspected and found by a nationally recognized testing laboratory to conform to specified plans or to procedures of applicable codes;

(d) Equipment is certified if it has been tested and found by a nationally recognized testing laboratory to meet nationally recognized standards or to be safe for use in a specified manner, or is of a kind whose production is periodically inspected by a nationally recognized testing laboratory, and if it bears a label, tag, or other record of certification.

(4) "Assistant Secretary" means the Assistant Secretary for Occupational Safety and Health or designee.

(5) "Automatic fire detection device" means a device designed to automatically detect the presence of fire by heat, flame, light, smoke or other products and effects.

(i) "Combination detector" means an automatic fire detection device which responds to more than one product of combustion.

(ii) "Flame detector" means an automatic fire detection device which detects the infrared or ultraviolet, or visible effects produced by a fire.

(iii) "Heat detector" means an automatic fire detection device which detects abnormally high temperature and/or rate-of-temperature rise.

(iv) "Line-type detector" means an automatic fire detection device in which detection is continuous along a path.

(v) "Other fire detectors" means automatic fire detection devices which detect phenomenon other than heat, smoke, light or flame produced by a fire.

(vi) "Smoke detector" means a device which detects visible or invisible particles of combustion.

(vii) "Spot-type detector" means a device whose detecting element is directed at a particular location.

(6) "Buddy breathing device" means an accessory to self-contained breath-

ing apparatus which permits a second person to share the same air supply as that of the wearer of the apparatus. Such devices are used for emergency escape situations.

(7) "Carbon dioxide" means a colorless, odorless, electrically nonconductive inert gas (chemical formula CO_2) that is a medium for extinguishing fires by reducing the concentration of oxygen or fuel vapor in the air to the point where combustion is impossible.

(8) "Class A fire" means a fire involving ordinary combustible materials such as paper, wood, cloth, rubber, and many plastics.

(9) "Class B fire" means a fire involving flammable or combustible liquids, flammable gases, greases, and similar materials.

(10) "Class C fire" means a fire involving energized electrical equipment where safety to the employee requires the use of electrically nonconductive extinguishing media.

(11) "Class D fire" means a fire involving certain combustible metals such as magnesium, titanium, zirconium, sodium, lithium and potassium.

(12) "Discharge alarm" means an alarm which sounds when an extinguishing agent is being discharged through a system.

(13) "Dry chemical" means a compound composed of very small particles of sodium bicarbonate, potassium bicarbonate, urea-based potassium bicarbonate, potassium chloride, or monoammonium phosphate supplemented by special treatment to provide resistance to packing and moisture absorption (caking) as well as to provide proper flow capabilities. Dry chemical does not include dry powders.

(14) "Dry powder" means a compound used to extinguish or control Class D fires.

(15) "Education" means the process of imparting knowledge or skill through systematic instruction. It does not require formal classroom instruction.

(16) "Enclosed structure" means a structure with a roof or ceiling which may present similar fire hazards to employees as buildings.

(17) "Extinguisher classification" means the letter classification given an extinguisher to designate the class or classes of fire on which an extinguisher will be effective for control or extinguishment of a fire. For example, a Class A extinguisher would be effective on Class A fires and a Class B:C extinguisher would be effective on Class B and Class C fires.

(18) "Extinguisher rating" means the numerical rating given to an extinguisher which indicates the extinguishing potential of the unit based on standardized tests developed by Underwriters' Laboratories, Inc.

(19) "Fire brigade" (private fire department and industrial fire department) means an organized group of employees who are knowledgeable, trained, and skilled in firefighting operations.

(20) "Fixed extinguishing system" means a permanently installed system that either extinguishes or controls a fire at the location of the system.

(21) "Flame resistance" is the property of materials, or combinations of component materials, to retard ignition and restrict the spread of flame.

(22) "Foam" means a stable aggregation of small bubbles which flow freely over a burning liquid surface and form a rigid air-excluding blanket which seals combustible vapors and thereby extinguishes the fire.

(23) "Gaseous agent" is a fire extinguishing agent which has a very low density and viscosity, can expand or contract with changes in pressure and temperature, and has the ability to diffuse readily and to distribute itself uniformly throughout an enclosure.

(24) "Halon 1211" means a colorless, faintly sweet-smelling electrically nonconductive liquefied gas (chemical formula CBrClF_2) which is a medium for extinguishing fires by inhibiting the chemical chain reaction of fuel and oxygen. It is also known as bromochlorodifluoromethane.

(25) "Halon 1301" means a colorless, odorless, electrically nonconductive gas (chemical formula CBrF_3) which is a medium for extinguishing fires by inhibiting the chemical chain reaction of fuel and oxygen. It is also known as bromotrifluoromethane.

(26) "Helmet" is a head protective device consisting of a rigid shell, energy absorption system, and chin strap intended to be worn to provide protection for the head or portions thereof, against impact, flying or falling objects, electric shock, penetration, heat and flame, or any combination thereof.

(27) "Incipient stage fire" means a fire which is in the initial or beginning stage and which can be controlled or extinguished by portable fire extinguishers or Class II standpipe systems without the need for protective clothing or breathing apparatus.

(28) "Inspection" means a visual check of fire protection systems and equipment to insure that they are in place, charged, and ready for use in the event of a fire.

(29) "Interior structural fire fighting" means the physical activity of fire suppression, rescue or both, inside of buildings or enclosed structures which are involved in a fire situation beyond the incipient stage.

(30) "Lining" means a material permanently attached to the inside of the outer shell for the purpose of thermal protection and padding.

(31) "Local application system" means a fixed suppression system which has a supply of extinguishing agent normally connected to fixed piping with nozzles arranged to automatically discharge extinguishing agent directly on the burning material to extinguish or control a fire.

(32) "Maintenance" means the services to be performed on fire protection equipment and systems to insure that they will perform as expected in the event of a fire. Maintenance differs from inspection in that maintenance requires the checking of internal fittings, devices and agent supplies. It requires, at least in part, the physical breakdown, disassembly and reassembly of the unit.

(33) "Multipurpose dry chemical" means a dry chemical which is approved for use on Class A, Class B and Class C fires.

(34) "Outer shell" is the exterior layer of material on the fire coat and protective trousers which forms the outermost barrier between the fire fighter and the environment. It is attached to the vapor barrier and liner and is constructed with a storm flap, suitable closures, and pockets.

(35) "Pipe schedule design" means a sprinkler system design which uses pipe specifications in a relationship between pipe size and the number of sprinklers permitted for each size by workplace classification.

(36) "Positive pressure breathing apparatus" means self-contained breathing apparatus in which the pressure inside the full facepiece is positive in relation to the immediate environment during inhalation and exhalation.

(37) "Pre-action alarm" or "Pre-discharge alarm" means an alarm which will sound at a set time prior to actual discharge of the system so that employees may evacuate the discharge area prior to system discharge.

(38) "Quick disconnect valve" means a device which starts the flow of air by insertion of the hose (which leads from the facepiece) into the regulator of self-contained breathing apparatus, and stops the flow of air by disconnection of the hose from the regulator.

(39) "Sprinkler alarm" means an approved device installed so that any waterflow from a sprinkler system equal to or greater than that from a single automatic sprinkler will result in an audible alarm signal on the premises.

(40) "Sprinkler systems" means a system of piping designed in accordance with fire protection engineering standards and installed to control or extinguish fires. The system includes an adequate and reliable water supply, and a network of specially sized piping and sprinklers which are interconnected. The system also includes a control valve and a device for actuating an alarm when the system is in operation.

(41) "Standpipe systems"—class of service.

(i) "Class II standpipe system" means a small hose system (1-1/2" or 3.81 cm) which provides a means for the control or extinguishment of incipient stage fires.

(ii) "Class II standpipe system" means a combined system of hose which is for the use of employees trained in the use of hose operations and which is capable of furnishing effective water discharge during the more advanced stages of fire in the inside of workplaces. Hose outlets are available for both large and small hose (1-1/2", 3.8 cm, and 2-1/2", 6.3 cm).

(42) "Total flooding system" means a fixed suppression system which is arranged to automatically discharge a predetermined concentration of agent into an enclosed space for the purpose of fire extinguishment or control.

(43) "Training" means the process of making proficient through instruction and practice. Training includes hands-on training of industrial fire brigades or emergency action teams in the duties they are expected to perform.

(44) "Vapor barrier" means that material used to prevent or substantially inhibit the transfer of water, corrosive liquids and steam or other hot vapors from outside of the garment to the wearer's body.

8. Section 1910.157 would be revised to read as follows:

§ 1910.157 Portable fire extinguishers.

(a) *Scope and application.* (1) These requirements shall apply to the placement, use, maintenance, and testing of portable fire extinguishers provided for the use of employees inside of workplace buildings and enclosed structures. Where an employer is using the exemption under paragraph (b)(1) of this section and where the extinguishers are provided but are not intended for employee use, the requirements of paragraphs (e) and (f) of this section shall apply.

(2) The requirements of paragraphs (c), (e), (f), and (g) of this section shall apply when an employer has provided extinguishers for employee use on the outside of workplace buildings or enclosure structures.

(b) *Exemptions.* (1) When the employer has established and implemented a written fire safety policy which requires the immediate and total evacuation of employees from the workplace upon the sounding of a fire alarm signal and which includes an emergency action plan and a fire prevention plan which meets the requirements of § 1910.38, the employer is exempt from the requirements of this section.

(2) When the employer has an emergency action plan meeting the requirements of § 1910.38 which designates

certain employees to be the only employees authorized to use the available portable fire extinguishers and where all other employees in the immediate fire area are required to immediately evacuate upon the sounding of the fire alarm, the employer is exempt from the distribution requirements in paragraph (d) of this section.

(c) *General requirements.* (1) The employer shall mount, locate and identify portable fire extinguishers so that they are readily accessible to employees without subjecting the employees to possible injury.

(2) The employer shall provide portable fire extinguishers currently approved to meet the requirements of this section.

(3) Carbon tetrachloride and chlorobromomethane extinguishing agents are prohibited from use in portable fire extinguishers used by employees.

(4) The employer shall maintain portable fire extinguishers in a fully charged and operable condition and keep them in their designated places at all times except during use.

(5) The employer shall permanently remove from service by January 1, 1982 all soldered or riveted shell self-generating soda acid or foam portable fire extinguishers which operate by inverting the extinguisher to initiate an uncontrollable pressure generating chemical reaction to expel the agent.

(d) *Selection and distribution.* (1) The employer shall select and distribute portable fire extinguishers for employee use in a manner determined by the classes of anticipated workplace fires and by the size or degree of hazard which would affect their use.

(2) The employer shall distribute portable fire extinguishers for use by employees on Class A fires so that the travel distance to any extinguisher is limited to 75 feet (23 meters) or less.

(3) The employer may use uniformly spaced small hose stations installed for emergency use by employees instead of Class A portable fire extinguishers provided that such small hose systems meet the requirements of 29 CFR 1910.158 and that they provide total coverage of the area to be protected.

(4) The employer shall distribute portable fire extinguishers for use by employees on Class B fires so that the travel distance to any extinguisher is limited to 50 feet (15 meters).

(5) The employer shall distribute portable fire extinguishers used for Class C hazards on the basis of the distribution patterns for the Class A or Class B fires associated with the Class C hazard.

(6) The employer shall distribute portable fire extinguishers or other containers of Class D extinguishing agent for use by employees so that the travel distance is limited to 75 feet (23

meters). Portable fire extinguishers for Class D hazards are required only in those combustible metal working areas where combustible metal powders, flakes, shavings, or similarly sized products are generated on a daily basis.

(e) *Inspection, maintenance, and testing.* (1) The employer shall be responsible for the inspection, maintenance and testing of those portable fire extinguishers provided for employee use in the workplace.

(2) The employer shall conduct monthly inspections.

(3) The employer shall record the inspection dates for each extinguisher and make the record available to the Assistant Secretary upon request. Such records shall be kept one year after entry.

(4) The employer shall subject portable fire extinguishers, except stored pressure units, to a maintenance check at least annually.

(5) The employer shall empty and subject stored pressure dry chemical and Halon 1211 extinguishers that require a 12-year hydrostatic test to the applicable maintenance procedures every 6 years.

(6) The employer shall replace portable fire extinguishers removed from service for maintenance and recharging with spare extinguishers having the same classification and at least equivalent rating.

(f) *Hydrostatic testing.* (1) The employer shall ensure that hydrostatic testing be performed by trained persons with suitable testing equipment and facilities.

(2) The employer shall hydrostatically test portable extinguishers at the intervals listed in Table L-1 of this section.

TABLE L-1

Type of extinguishers	Test interval (yrs.)
Soda acid (soldered brass shells) (until 1/1/82).....	*not permitted
Soda acid (stainless steel shell).....	5
Cartridge operated water and/or antifreeze.....	5
Stored pressure water and/or antifreeze.....	5
Wetting agent.....	5
Foam (soldered brass shells) (until 1/1/82).....	*not permitted
Foam (stainless steel shell).....	5
Aqueous film forming Foam (AFFF).....	5
Loaded Stream.....	5
Dry chemical with stainless steel or soldered brass shell.....	5
Carbon dioxide.....	5
Dry chemical, stored pressure, with mild steel brazed brass or aluminum shells.....	12
Dry chemical, cartridge or cylinder operated, with mild steel.....	12
Halon 1211.....	12
Halon 1301.....	12
Dry powder, cartridge or cylinder operated with mild steel shells ..	12

*Extinguishers having shells constructed of copper or brass joined by soft solder or rivets shall not be hydrostatically tested and shall be removed from service by January 1, 1982.

(3) The employer shall hydrostatically test portable extinguishers when they show evidence of corrosion or mechanical injury.

(4) The employer shall perform hydrostatic tests on extinguisher hose assemblies which are equipped with a shutoff nozzle at the discharge end of the hose. The test interval shall be the same as specified for the extinguisher on which the hose is installed.

(5) The employer shall test carbon dioxide extinguishers and nitrogen or carbon dioxide cylinders used with wheeled extinguishers at 5/6's of the service pressure as stamped into the cylinder every 5 years.

(6) The employer shall hydrostatically test all stored pressure and Halon 1211 types of extinguishers at the factory test pressure not to exceed two times the service pressure.

(7) The employer shall test acceptable self-generating type soda acid or foam extinguishers at 350 psi (2400 kPa).

(8) The employer shall test carbon dioxide hose assemblies requiring a hydrostatic pressure test at 1,250 psi (8,750 kPa).

(9) The employer shall test dry chemical and dry powder hose assemblies requiring a hydrostatic pressure test at 300 psi (2,100 kPa).

(10) The employer shall not use air or gas pressure for pressure testing.

(11) When extinguisher shells, cylinders, or cartridges fail a hydrostatic pressure test, the employer shall remove them from service and from the workplace.

(12) The equipment for testing cylinders and cartridges shall be of the water jacket type. The equipment shall be equipped with an expansion indicator which operates with an accuracy within 1% of the total expansion or .1cc of liquid.

(13) The employer shall test hose assemblies of carbon dioxide extinguishers that require a hydrostatic test within a protective cage device.

(14) In addition to the visual examinations required prior to testing, the employer shall also make an internal examination prior to the hydrostatic tests.

(15) The employer shall maintain and provide upon request to the Assistant Secretary evidence that the required hydrostatic testing of fire extinguishers has been performed at the time intervals shown in Table L-1. Such evidence shall include the date of test, the test pressure used, and the name or identification of the person or agency performing the test. Such records shall be kept for twelve years or as long as the extinguisher is in service whichever is less.

(16) Hose assemblies passing a hydrostatic test do not require any type of recording or stamping.

(g) *Training and education.* (1) Where the employer has provided portable fire extinguishers for employee use in the workplace, the employer shall provide an educational program to familiarize employees with the general principles of fire extinguisher use and the hazards involved with fighting fire of limited size.

(2) The employer shall provide the education required in paragraph (g)(1) of this section upon initial employment and at least annually thereafter.

(3) The employer shall provide employees, who have been designated to use fire fighting equipment as part of an emergency action plan, with hands-on training in the use of the appropriate equipment.

(4) The employer shall provide the hands-on training required in paragraph (g)(3) of this section upon initial assignment to the designated group of employees and at least annually thereafter.

9. Section 1910.158 would be revised to read as follows:

§ 1910.158 Standpipe and hose systems.

(a) *Scope and application.*—(1) *Scope.* This section contains the requirements for the components, water supply, testing and maintenance of standpipe and hose systems installed to meet the requirements of any OSHA standard.

(2) *Application.* This section applies to Class II and Class III systems which are installed for the use of employees.

(3) *Exception.* This section does not apply to Class I systems which are installed for use by full-time fire fighters trained in the handling and use of heavy hose streams.

(b) *Protection of standpipes.* The employer shall locate or otherwise protect standpipes against mechanical damage. Damaged standpipes shall be repaired promptly.

(c) *Equipment.*—(1) *Closets and cabinets.* Where reels or cabinets are provided to contain fire hose, the employer shall design them to facilitate prompt use of the hose valves, the hose, and other equipment at the time of fire or other emergency. The employer shall conspicuously identify and use reels and cabinets for fire equipment only.

(2) *Hose outlets and connections.* (i) The employer shall locate hose outlets and connections high enough above the floor to avoid being obstructed and to be accessible to employees.

(ii) Where the pressure under static or dynamic conditions at any standpipe outlet exceeds 100 psi (700 kPa), the employer shall install an approved device at the outlet to reduce the pressure at the outlet to 100 psi (700 kPa) or less with the required water flow.

(iii) The employer shall standardize screw threads throughout the system

and ensure that they are compatible with those used on supporting fire equipment. Use of adapters is permitted to provide compatibility.

(3) *Hose.* (i) The employer shall equip each 1½ inch hose outlet with fire hose attached and ready for use.

(ii) The employer shall equip standpipe systems installed after July 1, 1980, for use by employees, with lined hose. Unlined hose may remain in use on existing systems. However, after the effective date of this standard, unlined hose which becomes unserviceable shall be replaced with lined hose.

(iii) Effective July 1, 1980, the employer shall provide hose of such length that friction loss resulting from water flowing through the hose will not decrease the pressure at the nozzle below 30 psi (210 kPa).

(4) *Nozzles.* Effective July 1, 1981 the employer shall equip standpipe hose with shut-off type nozzles.

(d) *Water supply.* The minimum water supply for standpipe and hose systems, which are provided for the use of employees, shall be sufficient to provide 100 gallons per minute (380 l/m) for a period of at least thirty minutes. The supply shall be sufficient to maintain a residual pressure of 65 pounds per square inch (455 kPa) at the topmost outlet with 100 gallons per minute (380 l/m) flowing.

(e) *Tests and maintenance.*—(1) *Acceptance tests.* (i) The employer shall hydrostatically test piping of new Class II and III systems including yard piping at not less than 200 psi (1400 kPa) for a period of at least 2 hours, or at 50 psi (350 kPa) in excess of normal pressure when such pressure is greater than 150 psi (1050 kPa).

(ii) The employer shall ensure that hose on all Class II and III systems installed after July 1, 1980, be hydrostatically tested with couplings in place, before being placed in service, at a pressure of not less than 200 psi (1400 kPa). This pressure shall be held for at least 14 seconds and not more than one minute during which time the hose shall not leak nor shall any jacket thread break during the test.

(2) *Maintenance and repairs.* (i) The employer shall keep water supply tanks filled to the proper level except during repairs. When pressure tanks are used the employer shall maintain proper pressure at all times except during repairs.

(ii) The employer shall keep valves in the main piping connections to the automatic sources of water supply fully open at all times except during repair.

(iii) The employer shall make inspections of systems at least semiannually and after each use to assure that all of the equipment and hose is in place, available for use, and in serviceable condition.

(iv) When any component of the system is found not to be serviceable the employer shall remove it from service immediately and replace it with equivalent protection.

(v) Hemp or linen hose on existing systems shall be unracked, inspected for deterioration, and reracked at least annually by the employer. The employer shall replace defective hose as specified in paragraph (c) (3) (ii) of this section.

(vi) The employer shall ensure that inspections are made by trained designated employees who can ensure that the equipment is in serviceable condition.

11. Section 1910.159 would be revised to read as follows:

§ 1910.159 Automatic sprinkler systems.

(a) *Scope and application.* (1) The employer shall install, maintain and test automatic sprinkler systems installed to meet other OSHA requirements in accordance with the requirements of this section.

(2) For automatic sprinkler systems used to meet OSHA requirements and installed prior to the effective date of this standard, the employer may continue compliance with the National Fire Protection Association (NFPA) or the National Fire Protection Association (NFPA) or the National Board of Fire Underwriters (NBFU) standard in effect at the time of the system's installation provided the older system is still in compliance with the appropriate NFPA or NBFU standard.

(b) *Exemptions.* Automatic sprinkler systems installed in workplaces for the sole purpose of providing property protection are exempt from the requirements of this section.

(c) *General requirements.*—(1) *Design.* (i) All automatic sprinkler designs used to comply with this standard, whether hydraulic or pipe schedule, shall be capable of providing the necessary discharge patterns, densities, and water flow characteristics for complete coverage in a particular workplace or zoned subdivision of the workplace.

(ii) The employer shall use only approved equipment and devices in the design and installation of automatic sprinkler systems used to comply with this standard.

(2) *Maintenance.* The employer shall properly maintain an automatic sprinkler system installed to comply with this standard at all times.

(3) *Acceptance tests.* The employer shall conduct proper acceptance tests on sprinkler systems installed for employee protection after the effective date of this standard and record the dates of such tests. Proper acceptance tests include the following:

(i) Flushing of underground connections.

(ii) Hydrostatic tests of piping in system.

(iii) Air tests in dry-pipe systems.

(iv) Dry-pipe valve operation.

(v) Test of drainage facilities.

(4) *Water supplies.* The employer shall provide every automatic sprinkler system with at least one automatic water supply. The water supply shall be capable of providing design water flow for at least 30 minutes. An auxiliary water supply or a mandatory employee evacuation plan shall be provided when the automatic water supply is out of service. Auxiliary water supplies are not required for systems of 20 or less sprinkler heads.

(5) *Hose connections for fire fighter use.* The employer may attach hose connections for fire fighting use to wet pipe sprinkler systems in other than high hazard workplaces provided that the water supply satisfies the designed demand for sprinklers and standpipes combined.

(6) *Protection of piping.* The employer shall protect automatic sprinkler system piping against freezing and exterior surface corrosion.

(7) *Drainage.* The employer shall install all dry sprinkler pipe and fittings so that the system may be totally drained.

(8) *Pipe cutting.* The employer shall not permit torch cutting as a means of modifying or repairing sprinkler systems.

(9) *Sprinklers.* (i) The employer shall use only approved sprinklers on systems.

(ii) The employer may use older style sprinklers to replace similar style sprinklers, but not for replacing standard sprinklers without a complete engineering review of the system.

(iii) The employer shall protect sprinklers which are located so as to be subject to mechanical injury from such injury with effective guards.

(10) *Sprinkler alarms.* On all sprinkler systems having more than twenty (20) sprinklers, the employer shall provide a local waterflow alarm which sounds an audible signal upon water flow through the system equal to that from a single automatic sprinkler.

(11) *Sprinkler spacing.* The employer shall space sprinklers to provide a definite maximum protection area per sprinkler, a minimum of interference to the discharge pattern by building or structural members, or building contents and suitable sensitivity to possible fire hazards. The minimum vertical clearance below and between heads and obstructions shall be 18 inches.

(12) *Hydraulically designed systems.* The employer shall identify hydraulically designed automatic sprinkler systems or portions thereof and indicate the location, number of sprinklers in the hydraulically designed section, and the basis of the design. Central

records may be used in lieu of signs at sprinkler valves provided the records are available for inspection and copying by the Assistant Secretary.

11. Section 1910.160 would be revised to read as follows:

§ 1910.160 Fixed extinguishing systems, general.

(a) *Scope and application.* (1) This section applies to all fixed extinguishing systems installed to meet a particular OSHA standard.

(2) This section also applies to fixed systems not installed to meet a particular OSHA standard, but which, by means of their operation, could expose employees to possible injury, death, or adverse health consequences. Such systems shall meet the requirements of paragraph (b)(4) through (b)(7) and (c) of this section.

(3) Systems covered in paragraph (a)(2) of this section installed in areas with no employee exposure are exempted from the requirements of this section.

(b) *General requirements.* (1) Fixed extinguishing systems, components, and agents shall be designed and approved for use on the specific fire hazards they are expected to control or extinguish.

(2) If for any reason a fixed extinguishing system becomes inoperable, the employer shall notify employees and take the necessary temporary precautions to ensure their safety until the system is restored to operating order. Any defects or impairments shall be properly corrected by competent personnel.

(3) The employer shall provide a distinctive alarm capable of being perceived above ambient noise or light levels on all systems in the protected area to indicate that the system is discharging.

(4) The employer shall provide a distinctive alarm capable of being perceived above ambient noise or light levels to warn employees against re-entry into discharge areas where the atmosphere remains hazardous to employee safety and health.

(5) The employer shall post hazard warning or caution signs at the entrance to, and inside of, areas protected by fixed extinguishing systems which use agents known to be hazardous to employee safety and health.

(6) The employer shall ensure that fixed systems are inspected annually by a person knowledgeable in the designed function of the system to ensure that the system is maintained in an operating condition.

(7) The employer shall check the weight and pressure of refillable containers at least semi-annually. If the container shows a loss in net content or weight of more than 5%, or a loss in pressure of more than 10%, it shall be

subjected to maintenance. Records of semi-annual checks shall be kept available at the workplace for at least six-months after entry.

(8) The employer shall weigh factory charged nonrefillable containers which have no means of pressure indication at least semi-annually. If a container shows a loss in net weight of more than 5% it shall be replaced.

(9) The employer shall record inspection and maintenance dates on the container or on a tag attached to the container.

(10) The employer shall train employees designated to inspect, maintain, operate, or repair fire extinguishing systems and periodically review their training to keep them up-to-date in the functions they are to perform.

(11) The employer shall not use chlorobromomethane or carbon tetrachloride as an extinguishing agent.

(12) The employer shall coat system components installed out of doors or in the presence of corrosive atmospheres to protect against corrosion.

(13) Automatic detection equipment shall be approved, installed and maintained in accordance with 29 CFR 1910.164.

(14) The employer shall assure that all systems are designed to operate properly between -20° F (-40° C) and 130° F (54° C). Systems designed for and installed in areas with climatic extremes shall also be capable of operation at the expected extreme temperature levels.

(15) In engineered systems, the employer shall assure that the rate of application of an agent is such that the designed concentration can be reached within 30 seconds of initial discharge.

(16) In systems using agent concentrations exceeding the maximum safe level for the agent, the employer shall assure that automatic actuation be by means of an approved automatic fire detection device installed and interconnected to an alarm system to ensure the safe egress of employees from the discharge area prior to actuation.

(17) The employer shall provide at least one manual station for discharge activation of fixed extinguishing system.

(18) The employer shall identify manual operating devices as to the hazard they protect.

(19) The employer shall provide, and make readily available, the personal protective equipment needed to rescue employees trapped in hazardous atmospheres created by an agent discharge near the protected area.

(20) The employer shall provide a means of egress from the discharge area in accordance with 29 CFR Part 1910, Subpart E.

(c) *Total flooding systems with potential health and safety hazards to*

employees. (1) The employer shall provide an emergency action plan in accordance with 29 CFR 1910.38 for each area within a workplace that is protected by a total flooding system which provides agent concentrations exceeding the maximum safe levels set forth in 29 CFR 1910.162.

(2) Those systems installed in areas where employees cannot enter during or after the system operates are exempt from this paragraph.

(3) The employer shall provide a predischage alarm which will operate at least 30 seconds before the system discharges on all total flooding systems under the scope of this paragraph.

13. Section 1910.161 would be revised to read as follows:

§ 1910.161 Fixed extinguishing systems, dry chemical.

(a) *Scope and application.* This section applies to all fixed extinguishing systems installed in accordance with 29 CFR 1910.160 and using dry chemical as the extinguishing agent.

(b) *Specific requirements.* (1) Dry chemical agents designed to be used in combination with foams or wetting agents shall be approved for such use.

(2) The employer shall not mix dry chemicals of different compositions together. Systems designed for use with one chemical shall not be refilled with any other type.

(3) When dry chemical discharge may cause visual obscuration, the employer shall provide a predischage alarm for employees to safely egress from the discharge area. The predischage alarm shall activate at least 30 seconds before release of the agent.

(4) The employer shall sample the dry chemical supply in all except stored pressure systems from the top center of the supply tank and near the tank wall, at least annually, to determine if lumps exist which are harder than will be easily crumbled or reduced to powder when dropped from a height of 4 inches (10 cm).

14. The heading for the existing § 1910.162 would be deleted and a new § 1910.162 would be added to read as follows:

§ 1910.162 Fixed extinguishing systems, gaseous agent.

(a) *Scope and application.* This section applies to all fixed extinguishing systems installed in accordance with 29 CFR 1910.160 and using a gas as the extinguishing agent. In some cases, the gas may be in a liquid state during storage.

(b) *Specific Requirements.* (1) Agents used for initial supply and replenishment shall be of the type approved for the system's application. Carbon dioxide obtained by dry ice

conversion to liquid is not acceptable unless it is processed to remove excess water and oil.

(2) The employer shall maintain inerting type gaseous extinguishing concentrations by minimizing leakage from the enclosure or by applying extra gas if necessary.

(3) The designed extinguishing concentration for surface fires shall be achieved with a minimum development of toxic decomposition products.

(4) The employer shall assure that the designed extinguishing concentration for deep-seated fires is maintained for at least seven minutes after the initial discharge. It shall also be maintained for a sufficient period of time to allow the smoldering to be extinguished and the material to cool to a point which reignition will not occur when the inert atmosphere is dissipated.

(5) The employer shall provide a maximum discharge time of 30 seconds to reach the design concentration on all gaseous agent systems.

(6) When fire brigades will perform designated emergency actions under the emergency action plan meeting the requirements of § 1910.38, the employer shall assure that an effective agent concentration be maintained for a sufficient period of time to allow for effective emergency actions.

(7) The employer shall provide a distinctive pre-action or pre-discharge alarm capable of being perceived above ambient light or noise levels when agent concentrations exceed the maximum safe level for employee exposure. The maximum safe levels for employee exposure without using personal protective equipment are as follows:

- (i) For carbon dioxide, 4%; or
- (ii) For Halon 1301, 10%; or
- (iii) For Halon 1211, 4%.

(8) The employer shall not use Halon 1301 in concentrations greater than 10% in areas normally occupied by employees unless the protected spaces are to be evacuated by employees immediately after discharge of the agent or sooner. Where egress from an area cannot be accomplished within one minute, the employer shall not use Halon 1301 in concentrations greater than 7%. Halon 1301 concentrations are permitted greater than 10%, but less than 15%, in areas not normally occupied by employees provided egress can be accomplished within 30 seconds. Where concentrations can exceed 15%, the employer shall prevent employee exposure to the gas.

(9) The employer shall not use Halon 1211 or carbon dioxide in areas normally occupied by employees except where safe emergency egress can be assured in less than 30 seconds from the time of agent discharge.

(10) The employer shall base the quantity of inerting type gaseous extinguishing agent required on the total rate of discharge needed to blanket the area or volume protected and the time that the discharge must be maintained to assure complete extinguishment.

15. Section 1910.163 would be revised to read as follows:

§ 1910.163 Fixed extinguishing systems, water spray and foam.

(a) *Scope and application.* This section applies to all fixed extinguishing systems installed in accordance with 29 CFR 1910.160 and using water or foam solution as the extinguishing agent. This section does not apply to automatic sprinkler systems which are covered under 29 CFR 1910.159.

(b) *Specific requirements.* (1) The employer shall not use foams to extinguish fires involving gases, liquified gases with boiling points below ambient workplace temperatures such as butane, butadiene, propane, or cryogenic liquids.

(2) The employer shall not use foams or water spray to extinguish fires in materials which react violently with water, such as metallic sodium and metallic potassium.

(3) The employer shall not use regular foams for polar solvent liquids.

(4) The employer shall not mix different types of foam concentrates because they may be incompatible.

(5) The employer shall not permit foams, other than alcohol foams, to be discharged through foam spray devices onto fires involving water soluble solvents in depths exceeding one inch (2.5 cm).

(6) The employer shall assure that water spray systems be designed so that extinguishment or control can be accomplished and so that all necessary surfaces can be cooled sufficiently to prevent "flash back" occurring after the system is shut off.

(7) The employer shall assure that drainage of water spray systems be directed to locations away from employee work areas.

16. The existing § 1910.164 would be renumbered § 1910.165 and a new § 1910.164 would be added to read as follows:

§ 1910.164 Fire detection systems.

(a) *Scope and application.* This section contains the requirements for automatic fire detection systems installed to meet the requirements of a particular OSHA standard.

(b) *Installation and restoration.* (1) The employer shall assure that all devices, combination of devices, and equipment constructed and installed to comply with this standard be ap-

proved for the purpose for which they are intended.

(2) The employer shall restore all fire detection systems and components to normal operating condition as promptly as possible after each test or alarm. Spare detection devices and components which are normally destroyed in the process of detecting fires shall be kept stocked in quantities and locations to be available for prompt restoration of the system.

(c) *Maintenance and testing.* (1) The employer shall maintain all systems in an operable condition.

(2) The employer shall test and adjust the sensitivity and reliability of fire detectors and the fire detection system as often as needed to maintain proper operating conditions.

(3) The employer shall assure that pneumatic and hydraulic operated detection systems installed after July 1, 1980, be equipped with supervised systems.

(4) The employer shall assure that the servicing, maintenance and testing of fire detection systems be performed by a trained person knowledgeable in the operations and functions of the system.

(5) The employer shall clean fire detectors, that need to be cleaned of dirt, dust or other particulates in order to be fully operational at regular and periodic intervals. The cleaning operation and checking procedure, and necessary sensitivity adjustments shall be done by a trained person knowledgeable in the proper function and servicing of the equipment.

(d) *Protection of fire detectors.* (1) The employer shall protect fire detection equipment installed out of doors or in the presence of corrosive atmospheres from corrosion. The employer shall provide detection equipment requiring protection from the weather with a canopy, hood, or other suitable protection.

(2) The employer shall locate or otherwise protect detection equipment so that it is protected from mechanical or physical impact.

(3) The employer shall support detectors independently of their attachment to wires or tubing.

(e) *Response time.* (1) The employer shall assure that fire detection systems installed primarily for the purpose of actuating fire extinguishment or suppression systems shall be designed to operate in time to control or extinguish a fire.

(2) The employer shall assure that fire detection systems installed for the purpose of employee alarm and evacuation be designed and installed to allow sufficient time for safe escape of employees.

(3) The employer shall not delay alarms or devices initiated by fire detector actuation more than 30 seconds

unless the actions are not necessary for immediate safety of employees. In such cases the emergency action plan shall assure employees be notified, or extinguishment be actuated, in sufficient time to assure the safety and health of employees.

(f) *Number, location and spacing of detecting devices.* The employer shall assure that the number, spacing and location of fire detectors is based upon design data obtained from field experience or tests, engineering surveys, the manufacturer's recommendations, or recognized testing laboratory listing.

17. A new § 1910.164a would be added to read as follows:

§ 1910.164a Employee alarm systems.

(a) *Scope and application.* (1) The requirements of this section shall apply to all emergency alarms or alarm systems installed and used to meet a particular OSHA standard. This section does not apply to those pre-discharge, discharge, or supervisory alarms required on various fixed extinguishing systems.

(2) The requirements in this section that pertain to maintenance, testing and inspection shall apply to all local fire alarm signaling systems used for alerting persons regardless of function.

(b) *General requirements.* (1) The employer shall provide employees with an alarm system which will provide sufficient reaction time to safely escape from a life threatening emergency in the workplace.

(2) The employee alarm shall be capable of being perceived above ambient noise or light levels by all employees in the affected portions of the workplace. Tactile devices may be used to alert those employees who would not be otherwise able to recognize the audible or visual alarm.

(3) The employee alarm shall be distinctive and recognizable to employees as a signal to perform actions designated under the emergency action plan.

(4) The employer shall explain the preferred means of reporting emergencies, such as by manual pull-box alarms or by telephone, to each employee. The employer shall post emergency telephone numbers near telephones, on employee notice boards, and other conspicuous locations.

(c) *Installation and restoration.* (1) The employer shall assure that all devices, components, combinations of devices or systems constructed and installed to comply with this standard be approved. Steam whistles, air horns, strobe lights or similar lighting devices, or tactile devices meeting the requirements of this section shall be considered acceptable in meeting this requirement for approval.

(2) The employer shall restore employee alarm systems to normal operating condition as promptly as possible after each test or alarm. The employer shall maintain a stock of the necessary spare alarm devices and components subject to wear or destruction in quantities and locations for prompt restoration.

(d) *Maintenance and testing.* (1) The employer shall maintain all employee alarm systems in operating condition.

(2) The employer shall make a test of the reliability and adequacy of the employee alarm system at bi-monthly intervals. A different actuation device shall be used in each test so that no individual device is used for two consecutive tests.

(3) The employer shall maintain or replace power supplies as often as is necessary to assure a fully operational condition. Back-up means of alarm shall be provided when systems are out of service (i.e., employee runners, telephone, etc.).

(4) The employer shall assure that employee alarm systems installed after July 1, 1980 be supervised in such a manner that system failure to remain operational will result in a positive notification to assigned personnel that a deficiency exists in the system.

(5) The employer shall assure that the servicing, maintenance and testing of employee alarms be done by persons trained in the designed operation and functions necessary for reliable and safe operation.

(e) *Manual operation.* (1) The employer shall ensure that manually operated pull boxes for use in conjunction with employee alarms be unobstructed, conspicuous and readily accessible. The employees shall not have to travel more than 200 feet (61 meters) to reach a manual pull box device or a telephone in the alarm system area.

(2) Manual fire alarm pull boxes shall be approved.

18. As renumbered (see proposed change no. 17), § 1910.165 would read as follows:

§ 1910.165 Fire brigades.

(a) *Scope and application.*—(1) *Scope.* This section contains requirements for the organization, training, and personal protective equipment of fire brigades.

(2) *Application.* The requirements of this section apply to employees who are members of fire brigades. The requirements of this section also apply to industrial fire departments or to "private" or contractual type fire departments. The requirements of this section do not apply to airport crash rescue or forest firefighting operations.

(b) *Organization.*—(1) *Organizational statement.* The employer shall pre-

pare and maintain a statement or written policy which establishes the existence of a fire brigade and which describes the functions that the fire brigade is to perform at the workplace and it shall be available for inspection by the Assistant Secretary or by employees or their designated representatives.

(2) *Personnel.* The employer shall ensure that employees who are expected to do interior structural fire fighting are physically capable of performing duties which may be assigned to them during emergencies or other operations. The employer shall not permit employees with known heart disease, epilepsy, or emphysema, to participate in fire brigade emergency activities unless permitted by a certificate from a licensed physician.

(c) *Training.* (1) The employer shall provide training commensurate with those functions that the fire brigade is expected to perform.

(2) The employer shall assure that training conducted frequently enough to assure that assigned duties and functions will be performed satisfactorily and in a safe manner so as not to endanger brigade members or other employees. At a minimum, training shall be conducted annually.

(3) The employer shall assure that training for members of the fire brigade includes hands-on training, where members operate the equipment which they are expected to use and perform those operations brigade members are expected to perform during emergency situations.

(4) The employer shall inform fire brigade members about special hazards to which they may be exposed during fire and other emergencies. They shall also be advised of any changes that occur in relation to the special hazards. The employer shall develop procedures that describe the actions to be taken in situations involving the special hazards.

(d) *Firefighting equipment.* The employer shall maintain and periodically inspect firefighting equipment to assure the safe operational condition of the equipment.

(e) *Protective clothing.* The following requirements apply only to those employees who perform interior structural firefighting. (1) *General.* (i) The employer shall ensure that protective clothing ordered or purchased after July 1, 1980, meets the requirements contained in this paragraph. As the new equipment is provided, the employer shall assure that all brigade members wear it. The employer shall assure that brigade members wear protective clothing meeting the requirements of this paragraph after July 1, 1985.

(ii) The employer shall assure that brigade members wear protective

clothing while performing interior structural firefighting.

(iii) The employer shall assure that protective clothing protects the head, body, and extremities, and consists of at least the following components: foot and leg protection; hand protection; body protection; eye, face and head protection.

(2) *Foot and leg protection.* (i) Foot and leg protection shall be achieved by one of the following methods: (a) Fully extended boots which meet the requirements of paragraph (e)(2) and which provide protection for the legs;

(b) Protective shoes or boots which meet the requirements of paragraph (e)(2) and which are worn in combination with protective trousers that meet the requirements of paragraph (e)(3).

(ii) Protective footwear shall meet the requirements of § 1910.136 for class 75 footwear. In addition, protective footwear shall be water-resistant for at least five inches (12.7 cm) above the bottom of the heel and shall be equipped with slip-resistant outer soles.

(iii) When tested in accordance with "Military Specification for Fireman's Boots," MIL-B-2885D (1973 and amendment dated 1975), protective footwear shall provide protection against penetration of the midsole by a size 8D common nail when at least 300 pounds of static force is applied to the nail.

(3) *Body protection.* (i) Body protection shall be coordinated with foot and leg protection to ensure full body protection for the wearer. This shall be achieved by one of the following methods: (a) Wearing of a fire-resistive coat meeting the requirements of this paragraph in combination with fully extended boots meeting the requirements of this paragraph;

(b) Wearing of a fire-resistive coat in combination with protective trousers both of which meet the requirements of this paragraph.

(ii) The performance, construction, and testing of fire-resistive coats and protective trousers shall be at least equivalent to the requirements of the National Fire Protection Association (NFPA) standard NFPA No. 1971-1975, "Protective Clothing for Structural Fire Fighting," with the following permissible variations in those requirements: (a) Liner may be detachable but the shell is not permitted to be worn without the liner while performing interior structural fire fighting.

(b) To achieve increased ventilation of trapped body heat, the outer shell and vapor barrier may be penetrated by ventilation openings protected by non-metallic flame resistant material equal to this standard.

(c) Tearing strength of the outer shell shall be a minimum of eight pounds in any direction.

(d) The criteria for flame resistance of the outer shell, including that of trim, after the removal of the test flame shall be:

Maximum after-flame 2.0 seconds
Maximum after-glow 4.0 seconds
Average char-length 6.0 inches

(e) The outer shell and lining may char or discolor but must retain heat resistance and shall not separate or melt when placed in a forced air laboratory oven at a temperature of 500°F (260°C) for a period of five minutes.

(4) *Hand protection.* (i) Hand protection shall consist of protective gloves or glove system which allow dexterity of hand movement and sense of feel for objects.

(ii) Exterior material of protective gloves shall provide resistance against abrasion, puncture, and absorption of liquids.

(iii) Exterior material of gloves shall be fire resistant. Materials shall be tested by Federal Test Method 191, method 5903 (1971); maximum allowable after flame shall be 2.0 seconds and the maximum char length shall be 4.0 inches (10.2 cm.).

(iv) Protective gloves or glove system shall provide thermal insulation. When tested in accordance with National Institute for Occupational Safety and Health (NIOSH) publication, "The Development of Criteria for Firefighters' Gloves; Vol. II: Glove Criteria and Test Methods" (1976), such thermal insulation shall be sufficient so that the temperature inside the palm and gripping surface of the fingers of the gloves shall not exceed 111°F (44°C) when gloves or glove system are exposed to 932°F (500°C) for five seconds at 4 psi (28 kPa) pressure.

(v) When design of the fire-resistive coat does not otherwise provide protection for the wrists, protective gloves shall have wristlets of at least 4.0 inches (10.2 cm) in length to protect the wrist area when the arms are extended upward and outward from the body.

(5) *Head, eye and face protection.* (i) Head protection shall consist of a protective head device with ear flaps and chin strap which meet the performance, construction, and testing requirements of the National Fire Safety and Research Office of the National Fire Prevention and Control Administration, U.S. Department of Commerce, which are contained in "Model Performance Criteria for Structural Fire Fighters' Helmets" (August 1977).

(ii) Protective eye and face devices which comply with § 1910.133 shall be used by brigade members when performing operations where the hazards of flying or falling materials are present and which may cause eye and face injuries. Protective eye and face

devices provided as accessories to protective head devices (face shields) are permitted when such devices meet the requirements of § 1910.133.

(iii) Fire brigade members wearing full facepieces of breathing apparatus meeting the requirements of § 1910.134 and paragraph (f) of this section, shall be acceptable as meeting the eye and face protection requirements of this paragraph.

(f) *Respiratory protection devices.*—(1) *General requirements.* (i) The employer shall assure that respiratory protective devices worn by brigade members meet the requirements contained in § 1910.134 and the requirements contained in this paragraph.

(ii) Approved self-contained breathing apparatus with full-facepiece shall be worn by brigade members while working inside buildings or confined spaces where there is dense smoke or an oxygen deficiency. Such apparatus shall also be worn during emergency situations involving toxic substances.

(iii) Approved self-contained breathing apparatus shall be acceptable if equipped with a "buddy breathing" device or a quick disconnect valve. If these accessories are used, they shall not cause damage to the apparatus, or restrict the air flow of the apparatus, or obstruct the normal operation of the apparatus.

(iv) Approved self-contained compressed air breathing apparatus shall be acceptable when used with approved cylinders from other approved self-contained compressed air breathing apparatus when such cylinders are of the same size and pressure rating. All compressed air cylinders used with self-contained breathing apparatus shall meet DOT and NIOSH criteria.

(v) Self-contained breathing apparatus shall have a minimum service life rating of 30 minutes in accordance with the methods and requirements of the Mine Safety and Health Administration (MSHA) and NIOSH.

(vi) The employer shall clean and recharge each breathing apparatus after each use. Self-contained breathing apparatus shall be stored in such a manner that it will be maintained in a clean and operable condition.

(vii) Self-contained breathing apparatus shall be provided with an indicator which automatically sounds an audible alarm when the remaining service life of the apparatus is reduced to within a range of 20 to 24 percent of its rated service time.

(2) *Positive-pressure breathing apparatus.*

(i) The employer shall assure that self-contained breathing apparatus purchased after July 1, 1980, be of the pressure-demand or other positive-pressure type when such apparatus is worn by brigade members while performing interior structural fire fight-

ing operations. Effective July 1, 1983, this requirement applies to all self-contained breathing apparatus when used while performing interior structural fire fighting.

(ii) This requirement does not prohibit the use of a combination type self-contained breathing apparatus where the apparatus can be switched from a demand to a positive-pressure mode. However, such apparatus shall be in the positive-pressure mode when brigade members are performing interior structural fire fighting operations.

(iii) Effective July 1, 1985, new positive-pressure breathing apparatus, including full-facepiece, shall be capable of performing in temperatures down to -20°F (-40°C) without malfunction or loss of respiratory protection to the wearer for the duration of the equipment.

§§ 1910.165, 1910.165a and 1910.165b [Revoked]

19. Sections 1910.165, 1910.165a and 1910.165b would be revoked.

20. It is proposed to amend 19 CFR Part 1010 by adding the following appendices after the appropriate subparts.

APPENDIX A TO SUBPART E—EMPLOYEE FIRE SAFETY PLANS

A. *Emergency Action Plan*—1. *Development.* Every employer is encouraged to develop an Emergency Action Plan (EAP). Small employers, those with 10 or fewer employees, may develop an EAP and convey it to their employees orally, but larger employers are encouraged to post the plan at the main entrance of buildings or other employee frequented areas as a reminder to employees. The employer should consult employees in the affected areas and company safety or fire safety officials, along with local fire safety officials and consultants knowledgeable in evacuation procedures and related hazards concerning the formation of the EAP. The employer should assure that the EAP provides for contingencies that could reasonably be expected because of the nature of the serious hazards in the workplace such as toxic gas leaks, power failure, fire or explosion.

2. *Refuge or safe areas.* The designation of refuge areas for safe evacuation should be determined and identified in the EAP. In a building divided into fire zones by fire walls, the refuge area may still be within the same building but in a different zone from where the emergency occurs. Exterior refuge or safe areas may include parking lots, open fields or streets which are located away from the site of the emergency and which provide sufficient areas to accommodate the employees. Employees should be instructed to move away from the exit discharge doors of the building, and to avoid congregating close to the building where they may hamper emergency operations.

3. *Employee notification.* The employer, as part of the effort to put the EAP into effect, should assure that all affected employees understand their responsibilities upon being alerted of an emergency. All new affected employees should be informed of what their responsibilities are under the plan during their job orientation. If an

emergency action team or fire brigade has been organized, its firefighting as well as evacuation assistance role should be included in the plan.

4. *Workplaces with more than one employer.* In buildings with several places of employment, employers are encouraged to coordinate their EAP with the other employers in the building. A building-wide or standardized plan for the whole building is acceptable provided each employer informs the employees of their duties and responsibilities under the plan. The standardized plan need not be kept by each employer in the multi-employer building, provided there is an accessible location within the building where the plan can be reviewed by affected employees. When multi-employer building-wide plans are not feasible, employers should coordinate their plans with the other employers within the building to assure that conflicts or confusion are avoided during times of emergencies. In multi-story buildings where more than one employer is on a single floor, it is essential that these employers coordinate their plans with each other to avoid conflicts and confusion.

5. *Reporting emergencies.* In small workplaces where direct vocal communication, such as shouting or loud talking by a person, is possible for alerting all employees of an emergency, then this system may be used as the alarm system. Where workplaces are so organized or arranged that a single person shouting an alarm will not be promptly perceived by all employees, then other methods such as telephones, a local fire alarm signalling system, loud speaker voice communication system or others would be necessary.

6. *Evacuation.* Delayed and partial evacuation may be used by employers, who will require designated employees to remain behind to shut down machinery, processes or other actions and then evacuate the area. Such delayed evacuation procedures should provide for contingencies when the emergency is so severe that employees should leave immediately and not remain behind for shutdown procedures. Partial evacuation may be used where the employer has designated certain employees as members of the fire brigade to remain and attack the fire or other hazard.

7. *Training.* In areas where handicapped employees are working, employers are encouraged to develop a buddy system, or other means of assisting the handicapped employee's evacuation. When the buddy system is used, the employer should instruct the employees in the evacuation procedures to be used.

b. *Fire Prevention Plans—1. Development.* Every employer is encouraged to develop a fire prevention plan to enhance employee awareness of workplace fire hazards. The employer should consult company fire safety officials, employees and local fire marshals before the plan is finalized. These consultation activities would assure that all ignition and fuel sources are included in the plan. The plan should include the maintenance schedule information that is necessary to assure the proper operation of plant equipment to avoid an unwanted fire. Housekeeping activities and related control of fuel sources should be fully addressed in the plan. Activities such as cleaning up after each shift and the disposal of combustible waste, should be part of the plan. The storage and handling of combustible raw materials such as flammable liquids, solids and

gases should be part of the plan. The employer is encouraged to designate a person or persons on each shift who can be responsible for handling complaints concerning malfunctioning equipment and poor housekeeping in work areas. These activities which take place only on the outside of buildings need not be included in the plan though the employer is encouraged to do so.

2. *Employee notification.* The employer as part of effort to put the plan into effect should assure that all affected employees are aware of what they are expected to do under the plan. All new employees should be informed during their job orientation of what their duties are under the plan. The maintenance crew or team should be fully informed of the plan requirements for malfunctioning equipment which may be an ignition source. Employee responsibilities under the plan may be accomplished by the use of job sheets for each work area or it can be written in the form of a plan of action for the overall workplace.

APPENDIX B TO SUBPART L

I. PORTABLE FIRE EXTINGUISHERS

A. *Mounting.* Portable fire extinguishers may be mounted on hooks, brackets, or other devices provided the device will adequately support the extinguisher. Extinguishers should be mounted at a height where employees can remove them from their mounting device without injury. In cases where extinguishers can be struck by moving vehicles such as tow-motors, elevating mounting boards may be used to lift the extinguisher up to a safe height provided the extinguisher can be lowered and ready for use within one minute.

B. *Selection and Distribution—1. Selection.* Extinguishers for protecting Class A hazards may be selected from the following types: water, foam, loaded stream, or multipurpose dry chemical. Extinguishers for Class B hazards may be selected from the following types: Halon 1301, Halon 1211, carbon dioxide, dry chemicals, foam, or loaded stream. Extinguishers for Class C

hazards may be selected from the following types: Halon 1301, Halon 1211, carbon dioxide, or dry chemical. Class D fire hazards pose a problem in that there are few approved agents available in the marketplace. What agents are available are generally limited to one or a single class of metal hazard. In cases when an approved agent is unavailable for a specific workplace Class D hazard, the following alternative agents are recommended for general use:

1. Foundry flux,
2. Graphite powder,
3. Dry sand,
4. Dry dolomite, and
5. Dry talc, (powder).

The above listed agents have the ability to control if not extinguish many Class D fires found in most industrial operations. Because water can increase the severity of a Class D fire, these agents must be kept dry. Additional agents can be found by referring to any general fire protection engineering publication. When the employer selects the types of extinguishers for use against other than Class D hazards, he should make sure that the extinguisher has been listed or approved by a nationally recognized testing laboratory. Such a list or approval assure the employer of the reliability of the unit he has purchased. For radioactive combustible metal hazards, the employer should contact the Nuclear Regulatory Commission for recommendations.

In the selection of an extinguisher, the employer should give consideration to the health and safety hazards involved in the maintenance and use of the unit. Bromotrifluoromethane (Halon 1301) and bromochlorodifluoromethane (Halon 1211) extinguishers contain extinguishing agents whose vapor has a low toxicity. However, their decomposition products can be more hazardous. Employees should be instructed about the hazards of breathing the decomposition vapors. Dry chemical extinguishers used in small unventilated work areas may reduce visibility for up to several minutes.

2. *Distribution.* The following tables give recommended distribution patterns for Class A and Class B fire extinguishers:

CLASS A HAZARDS

	Hazard classification		
	Low	Ordinary	High
Minimum extinguisher rating	1A	2A	2A
Maximum floor area/unit of A	3,000 sq. ft.	1,500 sq. ft.	1,000 sq. ft.
Maximum floor area/extinguisher	11,250 sq. ft.	11,250 sq. ft.	11,250 sq. ft.
Maximum travel distances	75 ft.	75 ft.	75 ft.

CLASS B HAZARDS

	Hazard classification		
	Low	Ordinary	High
Basic minimum rating	5B/10B	10B/20B	20B/40B
Maximum travel distance	30 ft./50 ft.	30 ft./50 ft.	30 ft./50 ft.

Even though these tables are recognized as being an acceptable means for compliance, they do not preclude other distributions which can be shown to provide for adequate employee life safety; alternative distribution is acceptable. For example, where an employer provides an employee fire brigade as permitted in paragraph 1910.157(b)(2), portable equipment can be installed on special trucks or in special storage areas known to the fire brigade. Such distributions should recognize and provide for OSHA's intent of providing employee life safety in a fire emergency. Distribution patterns for Class C hazards should be based upon the Class B patterns. Distribution of Class D extinguishers should be based upon the 75 foot travel distance requirement in the standards.

C. Inspection, maintenance and testing. A reputable fire equipment servicing agency is usually the most reliable means available to the employer for having maintenance and recharging performed. Larger employers may find it desirable to establish their own maintenance and recharge facilities and train employees to perform these functions. In such cases the service manuals and parts lists for the equipment should be obtained from the extinguisher manufacturer. Any employer who elects to inspect, maintain or test portable fire extinguishers should become familiar with the methods and equipment recommended in the references in Appendix C.

D. Installation. Portable fire extinguishers installed and maintained in accordance with NFPA No. 10-1975 Standard for Portable Fire Extinguishers, are considered in compliance with this standard.

II. STANDPIPE AND HOSE SYSTEMS

A. Pre-fire planning. It is suggested that a pre-fire plan be coordinated with the local fire department. Such a plan would eliminate the unnecessary handling of hose by arriving fire departments. It would also assure that hose couplings used by the plant and the local fire department would be compatible.

B. Protection of standpipes: Standpipes may be protected by guards such as expanded metal cages, enclosure in walls, or bumper poles. Standpipes are considered damaged when they have been punctured or ruptured, creased or dented enough to restrict water flow, or have had components such as valves, valve wheels or handles or other devices removed or broken.

C. Equipment. 1. Hose should be considered unserviceable when it is visually inspected and found to be punctured, rotted, mildewed, or similarly damaged. Other standpipe and hose system equipment should be considered unserviceable when it is no longer capable of providing the service for which it was approved.

2. Hemp or linen hose can become damaged if it is not properly dried after use. If this hose is stored in a damp or wet condition, it will deteriorate.

3. Spray-type nozzles provide more effective fire control than straight-stream types. Solid stream nozzles may contribute to the spread of a fire by scattering burning materials. Employers should assure that employees are aware of the type of nozzles used on workplace hose systems.

4. Standardized hose coupling screw threads are necessary to provide effective use of fire hose provided by different fire companies. The American National Fire Hose Connection Screw Thread should be

used whenever it complements existing equipment. However, certain geographical areas of the country have adopted other standard threads. The employer is encouraged to check with local supporting fire departments to determine what thread is used so that equipment purchased for use in the workplace can be compatible.

D. Design and installation. Standpipe and hose systems designed and installed in accordance with NFPA Standard No. 14-1976, Standpipe and Hose Systems, are considered in compliance with this standard.

III. AUTOMATIC SPRINKLER SYSTEMS

A. Design and installation. Automatic sprinkler systems should be designed by professionals trained in the use of pipe schedules or hydraulic design principles. A reputable sprinkler installation firm can determine the necessary discharge patterns, densities and water flow characteristics for adequate employee safety and should be contracted for such work. Automatic sprinkler systems designed and installed in accordance with NFPA Standard No. 13, Automatic Sprinkler Systems may be considered as being in compliance with this standard. Many workplaces contain automatic sprinkler systems which were designed and installed many years ago in accordance with standards in effect at that time. These systems are acceptable for the purposes of this section, if there is an adequate water supply, piping system, and sprinkler pattern available to assure employee safety.

B. Maintenance. Back-up protection for automatic sprinkler systems being repaired may be provided in the affected areas by hose lines, portable extinguishers, partial evacuations, fire watches, or similar preventive measures.

Sprinkler system valves and devices can be protected from damage by enclosing them in cage-type guards or by placing protective barriers around them.

The employer is encouraged to provide a supply of spare sprinklers, of the type used on each system, near the sprinkler valve.

Employers are encouraged to install supervisory control systems on sprinkler systems to alert them of closed valves, loss of air pressure on dry pipe systems or other malfunctions which may affect employee safety.

C. Water supply. Auxiliary water supplies include fire department connections, gravity tanks, pumps and a cistern or pond, or a pressure tank.

D. Protection of piping. System piping can be protected from freezing by using dry pipe systems in unheated areas. Heating protected areas or insulating piping can protect wet pipe systems from freezing. System piping can be protected for exterior surface corrosion by coating with paint or other coating. Approved corrosion resistant sprinklers are available. Fusible links on sprinklers should not be painted because it reduces their effectiveness.

E. Sprinkler spacing. The employer should use the services provided by professional sprinkler system designers to determine what spacings and clearances are necessary to provide maximum protection.

IV. FIXED EXTINGUISHING SYSTEMS, GENERAL

A. Design. Fixed extinguishing systems are permanent in their location and installation. They use any of several agents such as dry chemical, foam, water spray, Halon 1211, or Halon 1301. They can be designed for local or total flooding applications. They

can be of a customized design for a specific hazard or of a pre-engineered design for more standardized hazard applications.

When the employer selects a fixed extinguishing system to meet an OSHA requirement, the selection should be based on the requirement and the following factors:

1. Size and class of hazard.
2. Employee exposure to the hazard and the agent.
3. Employee safety and health considerations associated with the agent. (See specific agent section.)

Systems which are designed and installed in accordance with applicable national consensus standards may be considered in compliance with the intent of this standard.

B. Employee safety. Warning or hazard signs should be posted so that they can be read from a distance of 10 feet or more. For those areas where employees may be trapped due to total flooding systems, the employer is encouraged to provide escape self-contained breathing apparatus of at least 5 minute service life in such areas.

C. Maintenance. Employers are encouraged to conduct an acceptance test of all new systems to assure that piping and valves are properly connected. Employers should install supervisory control systems on all major operated valves to better assure the systems are ready for use.

V. FIXED EXTINGUISHING SYSTEMS, DRY CHEMICALS

A. Design and installation. The dry chemical systems described in § 1910.161 are designed to discharge a dry chemical from fixed nozzles and piping, or from hose lines by means of an expellant gas. The intent of the standard is to present the design considerations applicable to those systems.

Employers are encouraged to perform acceptance tests on new dry chemical systems by discharging the expellant gas and checking for major gas leaks in the piping and valves.

Dry chemical extinguishing systems installed in accordance with NFPA Standard No. 17, Dry Chemical System, may be considered in compliance with this standard.

B. Hazards to employees. Dry chemical fire extinguishing agents are considered nontoxic. However, as with any finely divided material, they may produce mild irritation effects especially when used in an enclosed area. In general, these effects are neither serious nor permanent. For more specific guidance on individual dry chemical extinguishing agent components and their hazards to personnel, the dry chemical manufacturer should be consulted.

VI. FIXED EXTINGUISHING SYSTEMS, GASEOUS AGENTS

A. Carbon Dioxide—1. The agent. As a fire extinguishing agent, carbon dioxide has a number of desirable properties. It is noncorrosive and leaves no residue to clean up after a fire. Since it is a gas, it will penetrate and spread to all parts of a hazard. It will not conduct electricity and may therefore be used on live electrical hazards. It may be effectively used on practically all combustible materials, except for a few reactive metals and metal hydrides and materials such as cellulose nitrate, which contain available oxygen. Under normal conditions carbon dioxide is an odorless, colorless gas with a density about 50 percent greater than the density of air. Many insist that they can detect an odor of carbon dioxide.

but this may be due to impurities or chemical effects in the nostrils.

2. *Toxicity.* Although carbon dioxide is only mildly toxic, it will definitely produce unconsciousness and death when present in fire extinguishing concentrations. The action in this case is related to suffocation more than to any toxic effect of the carbon dioxide itself. It has been determined by test that atmospheres containing 3 or 4 percent carbon dioxide will cause one to breathe rapidly, but will otherwise have no important effect for relatively short exposures. A concentration of about 9 percent is about all most people can withstand without losing consciousness within a few minutes. At concentrations above 9 percent, personnel would quickly lose consciousness. At concentrations of about 20 percent, death would follow in about 20 to 30 minutes unless the victim was removed to fresh air. Recovery by artificial respiration is usually rapid because of the natural tendency of carbon dioxide to promote breathing. Aside from the normal effect of carbon dioxide causing unconsciousness, it should be noted, that even before this happens, there may be a marked inability to think clearly and to take prompt action. This effect is important because inexperienced personnel may fail to take proper action if suddenly exposed to relatively high concentrations of carbon dioxide.

3. *Employee hazards.* In most cases the actual hazard to personnel is rather slight. The hazard will be greater where the enclosure is large and where carbon dioxide may enter unsuspected areas such as pits or basements. The difficulty of escaping from a given location, and the possibility of reduced visibility because of a discharge of carbon dioxide may also be important factors. In any case, the extent and type of warning to personnel must be designed to meet the particular requirements of each situation.

4. *Employee safeguards.* The steps and safeguards necessary to prevent injury or death to personnel in atmospheres made hazardous by the discharge of carbon dioxide may include the following:

- Provision for adequate aislesways and routes of exits and keeping them clear at all times.
- Provision for the necessary additional emergency lighting and directional signs to ensure quick, safe evacuation.
- Provision for alarms within such areas that will operate immediately upon detection of the fire, with the discharge of the carbon dioxide and the activation of automatic door closures, delayed for sufficient time, to evacuate the area before discharge begins.
- Provisions for outward swinging self-closing doors at exits from hazards areas, and, where such doors are latched, provision for panic hardware.
- Provision for continuous alarms at entrances to such areas until the atmosphere has been restored to normal.
- Provision for adding an odor to the carbon dioxide so that hazardous atmospheres in such areas can be recognized.
- Provision for warning and instruction signs at entrances to and inside of such areas.
- Provision for prompt discovery and rescue of persons rendered unconscious in such areas. This may be accomplished by having such areas searched immediately after carbon dioxide discharge ceases by

trained employees equipped with proper self-contained breathing apparatus. Self-contained breathing apparatus and personnel trained in its use, and in rescue practices, including artificial respiration, should be readily available.

i. *Provision for instruction and drills* for all personnel within, or in the vicinity of such areas, including maintenance personnel who may be brought into the area, to ensure their correct action when carbon dioxide protective equipment operates.

j. *Provision for means for prompt ventilation.* Care should be taken to readily dissipate hazardous atmosphere and not merely move them to another location.

5. *Design and installation.* Carbon dioxide systems installed in accordance with NFPA Standard No. 12-1977, Carbon Dioxide Systems, are considered in compliance with this standard.

6. *Acceptance tests.* Employers are encouraged to have an acceptance test performed on all new systems to assure that all components of the system will operate properly.

B. *Bromotrifluoromethane (Halon 1301).*—1. *The agent.* Halon 1301 is a halogenated compound. Discharge of the agent may create a light mist in the vicinity of the discharge nozzle, resulting from condensation of moisture in the air, but the mist rarely persists after discharge is completed. Thus, little hazard is created from the standpoint of reduced visibility.

2. *Toxicity.* The discharge of Halon 1301 to extinguish a fire may create a hazard to personnel from the compound and from the products of decomposition that result from exposure of the agent to fire or other hot surfaces. Exposure to Halon 1301 is generally of less concern than exposure to the decomposition products. However, unnecessary exposure of personnel to either the Halon 1301 or to the decomposition products should be avoided. Undecomposed Halon 1301 has been studied in humans and found to produce minimal, if any, central nervous system effects at concentrations below 7 percent for exposures of approximately 5 minutes' duration. At concentrations of 7 to 10 percent, effects such as dizziness, impaired coordination, and reduced mental acuity become definite with exposures of a few minutes duration; however, these effects are not incapacitating for exposures of one minute or less. At concentrations above 10 percent, these effects increase in intensity and may become incapacitating with exposures longer than one minute. At concentrations of 15 to 20 percent, there is the risk of unconsciousness and possibly death if the exposure is prolonged. Personnel should not attempt to remain in an area following discharge of Halon 1301 in concentrations above 7 percent. It is recommended that they do not remain in an area for more than 4 or 5 minutes even though agent concentrations are below 7 percent. Within the first 30 seconds of exposure to Halon 1301 little effect is noticed, even when concentrations of 10 to 15 percent are inhaled. At these levels, this amount of time appears necessary for the body to absorb a sufficient quantity of the agent to bring about the onset of effects. However, at higher concentrations, the onset of symptoms may occur within a few seconds and, since an individual may be quickly incapacitated by these higher levels, concentrations great than 15 percent should not be used where there is any chance of human exposure. The effects of exposure to

Halon 1301 may persist for a short period of time following exposure. However, recovery may be expected to be rapid and complete. Halon 1301 would not be expected to accumulate in the body even with repeated exposures. Anyone suffering from the toxic effects of Halon 1301 vapors should immediately move or be moved to fresh air. In treating persons suffering toxic effects due to exposure to this agent, the use of epinephrine (adrenaline) and similar drugs must be avoided because they may produce cardiac arrhythmias, including ventricular fibrillation.

3. *Employee safeguards.* The steps and safeguards necessary to prevent injury or death to personnel in atmospheres made hazardous by the discharge or thermal decomposition of Halon 1301 are the same as those for carbon dioxide described earlier.

4. *Design and installation.* Halon 1301 systems installed in accordance with the design requirements of the National Fire Protection Association's Standard for the Installation of Halogenated Fire Extinguishing Agent Systems—1301, NFPA No. 12A-1977, are considered in compliance with the requirements of this Standard.

5. *Acceptance tests.* The employer is encouraged to have acceptance tests performed on all new systems to assure that the system will function properly.

C. *Bromochlorodifluoromethane (Halon 1211).*—1. *The agent.* Halon 1211 is a colorless gas with a faintly sweet smell and having a density about 5 times that of air. The fire extinguishing characteristics are similar to those of Halon 1301, and reference should be made to that discussion for information.

2. *Toxicity.* The hazards to employees from the discharge of Halon 1211 are also similar to those of Halon 1301, but because of the differences in concentrations, the following is presented. Exposure to Halon 1211 and its products of decomposition may be hazardous. Halon 1211 has been studied in humans and found to produce minimal, if any, central nervous system effects at concentrations below 4 percent for exposures of approximately one minute duration. At concentrations above 4 percent, effects such as dizziness, impaired coordination and reduced mental acuity become definite with exposure of a few minutes duration. However, these effects are not incapacitating for exposure of one minute or less. Within the first 30 seconds of exposure to Halon 1211, little effect is noticed, even when concentrations above 4 percent are inhaled. At these levels 30 seconds appears to be the time necessary for the body to absorb a sufficient quantity of agent to bring about the onset of effects. At concentrations on the order of 5 to 10 percent, there is the risk of unconsciousness and possible death if the exposure is prolonged. The effects of exposure of Halon 1211 may persist for a short period of time following exposure. However, recovery may be expected to be rapid and complete. Halon 1211 would not be expected to accumulate in the body even with repeated exposures. The decomposition products of Halon 1211 are the same as Halon 1301 with the addition of some chlorine compounds and acids (HCl, Cl₂, and COCl₂).

3. *Employee safeguards.* The safety steps and safeguards for Halon 1211 are the same as those for Halon 1301 and carbon dioxide.

4. *Design and Installation.* Additional design considerations and information can be found in the National Fire Protection As-

sociation's Standard for Halogenated Fire Extinguishing Agent Systems—Halon 1211, NFPA 12B.

Halon 1211 extinguishing systems installed in accordance with design requirements of the National Fire Protection Association's Standard for the Installation of Halogenated Fire Extinguishing Agent Systems—Halon 1211, NFPA 12B may be considered to be in compliance with the design requirements of this standard.

Employers are encouraged to have acceptance tests performed on all new systems to assure that the system is ready for use.

VII. FIXED EXTINGUISHING SYSTEMS WATER SPRAY AND FOAM AGENTS

A. The agent. Foam for fire protection purposes is an aggregate of air-filled bubbles formed from aqueous solutions and is lower in density than the lightest flammable liquids. It is used to form a coherent floating blanket on flammable and combustible liquids lighter than water and prevents or extinguishes fire by excluding air and cooling the fuel. It also prevents reignition by suppressing formation of flammable vapors. It has the property of adhering to surfaces, providing a degree of exposure protection from adjacent fires.

B. Toxicity. Generally, foams do not present a toxic hazard when used as a fire extinguishing agent.

C. Employee hazards. A space filled with high expansion foam is normally not toxic to persons who may be trapped in the space, since the air entrained in the foam is generally not contaminated. However, because of the foam bubbles, some difficulty may be experienced in breathing. Additionally, there is the possibility of the loss of vision and disorientation in the atmosphere of high expansion foam. Because of the potential presence of life safety and injury hazards, entering a foam-filled space should be avoided. When necessary, a coarse water spray may be used to "cut" a path in the foam and personnel should wear self-contained breathing apparatus and a lifeline when entering an area filled with foam.

D. Design and installation. Fixed water spray or foam extinguishing systems installed in accordance with design requirements of the National Fire Protection Association's Standard for the Installation of Foam Extinguisher Systems, NFPA No. 11-1976; High Expansion Foam Systems, NFPA No. 11A-1976; or Foam-Water Systems, NFPA No. 16-1974 are considered in compliance with the design requirements of this section.

E. Storage considerations. Since all air foam concentrates are water solutions of organic and inorganic chemicals of one type or another, they must be carefully observed for changes in constitution and characteristics. Their storage in shipping containers and in storage tanks must be carried out according to the manufacturer's recommendations. Exposure to extreme heat, cold, contamination, or mixing with other materials must be avoided. Sedimentation or precipitate formation on containers or tanks of concentrate should be carefully checked periodically. The manufacturer or his representative is best qualified to test and determine the extent of reliability of foam concentrates under questionable conditions of deterioration of these liquids.

F. Acceptance tests. Employers are encouraged to have acceptance tests performed on

all new systems to assure that the system will function properly.

G. Drainage. Drainage may be provided with pipe systems above or below ground, curbing, trenches, or ditches. The drainage should carry any overflowing liquids to a safe place away from employees.

VIII. FIRE DETECTION SYSTEMS.

A. Mounting. 1. *Locations.* Areas where fire detectors should be mounted include: rooms, halls, storage areas, basements, attics, lofts, spaces above suspended ceilings, inside of closets, elevator shafts, enclosed stairwells, dumbwaiter shafts, chutes, and return air ducts on ventilation systems. Other locations may be necessary depending upon workplace hazards.

2. *Ceilings.* Consideration should be given to ceiling configurations when mounting detectors. Heat and smoke will rise to the highest point inside of a workplace; however, a detector will ordinarily operate sooner if it is nearer to a potential fire source. Generally, height is the most important single dimension where ceilings exceed 16 feet.

b. Spacing. Detectors should be spaced in accordance with the manufacturer's recommendations or in consideration of a nationally recognized testing laboratory's recommendation. Reduction of listed spacing may be required for any of the following purposes:

- Need for faster response.
- Need for small fire response.
- Need to accommodate room geometry.
- Need to consider air movement, ceilings or other obstructions.

C. Design and installation. Fixed detection systems designed and installed in accordance with NFPA Standard No. 72-1974, Automatic Fire Detectors, are considered in compliance with this standard.

IX. EMPLOYEE ALARM SYSTEMS

A. Purpose. Employee alarm systems are not necessarily the typical fire alarm pull box interconnected with an alarm gong, bell or horn. In some places the alarm systems may contain a steam whistle, air horns, flashing lights, verbal instructions given either directly or by means of a public address system or a similar means of indicating an emergency. This system may be used to signal not only a fire but also an approaching storm hazard (tornado) or a geophysical hazard such as an earthquake or flood. As long as the signal is recognized by the employees as one indicating a life safety hazard, the system may be multi-purpose.

B. Testing. Pull boxes, detectors or other actuating devices may be an integral part of an alarm system. Every actuating device on an alarm system should be tested on a rotational basis to assure their operability. Manufacturer or listing agency recommendations give safe procedures for testing detectors and pull boxes.

C. Alarm signals. Employers are encouraged to develop distinctive signals for each anticipated emergency. A single bell, horn or light signal for every emergency can lead to confusion and misinterpretation of the alarm one ring, two rings, one long and one short ring, or something similar for each emergency is an effective method of notifying employees that a specific emergency exists.

X. FIRE BRIGADES

A. Pre-fire planning. It is suggested that the local fire department or fire prevention

bureau be consulted for additional information which may be helpful in understanding and in the implementation of this section.

A pre-fire plan of the workplace by the local fire department in conjunction with the fire brigade, is encouraged. This will also be valuable for the local fire department in becoming familiar with the workplace and its activities.

B. Organizational statement. The organizational statement should include at least the following information: The purpose for which the brigade was organized; intended size of the brigade; number of hours brigade members are to work in relation to brigade functions; type and frequency of training; and duties which are to be performed by brigade members.

C. Physical qualifications. Physical qualifications can be determined by such methods as preplacement physical examinations, physical agility tests, and periodic physical reexamination while the employee is a member of the brigade. Employees with coronary or respiratory illnesses should not serve as brigade members performing emergency operations unless permitted by a doctor's certificate.

It is also recommended that brigade members participate in a physical fitness program. There are many benefits which can be attributed to being physically fit. It is believed that physical fitness may help to reduce the number of sprain and strain injuries as well as contributing to the improvement of the cardiovascular system.

D. Training. The paragraph on training does not contain specific training requirements because the type, amount, and frequency of training will be as varied as are the purposes for which brigades are organized.

However, it is obvious that brigade members who are expected to perform interior structural firefighting should require training which is more comprehensive and more frequent than those brigade members who are only expected to control or extinguish fires in the incipient stage.

The following recommendations should not be considered to be all of the necessary elements for a complete comprehensive training program; but, the information may be helpful as a guide in developing a fire brigade training program.

All brigade members should be familiar with exit facilities, location and emergency escape routes for handicapped workers, and the workplace "emergency action plan."

In addition, brigade members who are expected to control and extinguish fires in the incipient stage should, at a minimum, be trained in the use of fire extinguishers, standpipes, and other fire equipment they are assigned to use. They should also be aware of first-aid medical procedures and procedures for dealing with special hazards to which they may be exposed. Training should include both classroom instruction and actual operation of the equipment under simulated emergency conditions. This type of training should be conducted at least annually but some functions should be reviewed more often.

In addition to the above training, brigade members who are expected to perform emergency rescue and interior structural fire fighting should, at a minimum, be familiar with the proper techniques in rescue and fire suppression procedures. Training should include fire protection courses, classroom training, simulated fire situations in-

cluding "wet drills" and, when feasible, extinguishment of actual mock fires. Frequency of training should be at least monthly, but some drills or classroom training should be conducted as often as weekly to maintain the proficiency of brigade members.

E. Protective clothing—1. General. Paragraph (e) of this section does not require all brigade members to wear protective clothing. It is not the intention of these standards to require employers to provide a full ensemble of protective clothing for every brigade member without consideration given to the types of hazardous environments to which the brigade member may be exposed. It is the intention of these standards to require adequate protection for those brigade members who may be exposed to fires in an advanced stage, smoke, toxic gases, and high temperatures.

Therefore, the protective clothing requirements only apply to those brigade members who are performing interior structural fire fighting operations.

Additionally, the protective clothing requirements do not apply to the protective clothing worn during outside fire fighting operations (brush and forest fires), crash crew operations, or other special fire fighting activities.

2. Foot and leg protection. Section 1910.165 permits an option to achieve foot and leg protection.

The section recognizes the interdependence of protective clothing to cover one or more parts of the body. Therefore, the option is given so that brigade members may meet the foot and leg requirements by either wearing long fire-resistant coats in combination with fully extended boots; or, by wearing shorter fire-resistant coats in combination with protection trousers and protective shoes or shorter boots.

3. Body protection. Paragraph (e)(3) of the section provides an option for brigade members to achieve body protection. Brigade members may wear a fire-resistant coat in combination with fully extended boots; or, they may wear a fire-resistant coat in combination with protective trousers.

Fire-resistant coats and protective trousers meeting all of the requirements contained in the NFPA 1971-1975, Protective Clothing for Structural Fire Fighters are acceptable as meeting the requirements of this standard.

4. Hand protection. The requirements of the paragraph on hand protection may be met by protective gloves or a glove system. A glove system consists of a combination of gloves. The usual components of a glove system consists of a pair of gloves, which provide thermal insulation to the hands, worn in combination with a second pair of gloves which provide protection against fire, abrasion, puncture, and absorption of liquids.

5. Head, eye, and face protection. The paragraph of the standard concerning head protection requires ear flaps to be provided with the protective head device so that they will be available if needed. It is recommended that ear protection always be used while fighting interior structural fires.

Many head protective devices are equipped with face shields to protect the eyes and face. These face shields are permissible as meeting the eye and face protection requirements of this paragraph as long as such face shields meet the requirements of § 1910.133 of the General Industry Standards.

Additionally, full facepieces of breathing apparatus meeting the requirements of § 1910.134 and paragraph (f) of § 1910.165 are also acceptable as meeting the eye and face protection requirements.

6. Respiratory protective devices. Since brigade members may be exposed to smoke and toxic substances while performing interior structural firefighting operations, it is imperative to assure maximum protection against facepiece leakage.

The use of a combination type self-contained breathing apparatus where the apparatus can be switched from a demand to a positive-pressure mode is also acceptable as long as the apparatus is in the positive pressure mode when performing interior structural fire fighting operations. Also acceptable are approved respiratory protective devices which have been converted to the positive-pressure type when such modification is accomplished by competent persons using kits or parts approved by NIOSH and provided by the manufacturer and by following the manufacturers' instructions.

The employer is encouraged to provide brigade members with an alternative means of respiratory protection to be used for emergency escape purposes if the self-contained breathing apparatus becomes inoperative.

Alternative means of respiratory protection may be either a buddy-breathing device or an escape self-contained breathing apparatus (ESCB). The ESCBA is a short-duration respiratory protective device which is approved only for emergency escape purposes.

It is suggested that if ESCBA units are used, that they be of at least 5 minutes service life.

APPENDIX C—REFERENCES FOR FURTHER INFORMATION

I. Appendix general references. The following references provide a vast amount of information which can be helpful in understanding the requirements contained in all of the sections of Subpart L:

A. Fire Protection Handbook. National Fire Protection Association; 470 Atlantic Avenue, Boston, MA 02210.

B. Accident Prevention Manual for Industrial Operations. National Safety Council; 425 North Michigan Avenue, Chicago, IL 60611.

C. Various associations also publish information which may be useful in understanding these standards. Examples of these associations are: Fire Equipment Manufacturers Association (FEMA) of Arlington, VA 22204 and the National Association of Fire Equipment Distributors (NAFED) of Chicago, IL 60601.

II. Appendix references applicable to individual sections. The following references are grouped according to individual sections contained in Subpart L. These references provide information which may be helpful in understanding and implementing the standards of each section of Subpart L.

A. § 1910.157. Portable fire extinguishers:

1. Standard for Portable Fire Extinguishers. NFPA 10; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. Methods for Hydrostatic Testing of Compressed Gas Cylinders. C-1; Compressed Gas Association, 500 Fifth Avenue, New York, NY 10036.

3. Recommendations for the Disposition of Unserviceable Compressed Gas Cylinders,

C-2; Compressed Gas Association, 500 Fifth Avenue, New York, NY 10036.

4. Standard for Visual Inspection of Compressed Gas Cylinders. C-6; Compressed Gas Association, 500 Fifth Avenue, New York, NY 10036.

5. Portable Fire Extinguisher Selection Guide. National Association of Fire Equipment Distributors; 111 East Wacker Drive, Chicago, IL 60601.

B. § 1910.158. Standpipe and hose systems:

1. Standard for the Installation of Sprinkler Systems. NFPA 13; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. Standard for the Installation of Standpipe and Hose Systems. NFPA 14; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. Standard for the Installation of Centrifugal Fire Pumps. NFPA 20; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. Standard for Water Tanks for Private Fire Protection. NFPA 22; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. Standard for Screw Threads and Gaskets for Fire Hose Connections. NFPA 194; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. Standard for Fire Hose. NFPA 196; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

7. Standard for the Care of Fire Hose. NFPA 198; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

C. § 1910.159. Automatic sprinkler systems:

1. Standard for the Installation of Sprinkler Systems. NFPA 13; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. Standard for the Care and Maintenance of Sprinkler Systems. NFPA 13A; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. Standard for the Installation of Standpipe and Hose Systems. NFPA 14; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. Standard for the Installation of Centrifugal Fire Pumps. NFPA 20; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. Standard for Water Tanks for Private Fire Protection. NFPA 22; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. Standard for Indoor General Storage. NFPA 231; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

7. Standard for Rack Storage of Materials. NFPA 231C; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

D. § 1910.160. Fixed extinguishing systems—general information:

1. Standard for Foam Extinguishing Systems. NFPA 11; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. Standard for Hi-Expansion Foam Systems. NFPA 11A; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. Standard on Synthetic Foam and Combined Agent Systems. NFPA 11B; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. *Standard on Carbon Dioxide Extinguishing Systems*, NFPA 12; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. *Standard on Halon 1301*, NFPA 12A; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. *Standard on Halon 1211*, NFPA 12B; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

7. *Standard for Water Spray Systems*, NFPA 15; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

8. *Standard for Foam-Water Sprinkler Systems and Foam-Water Spray Systems*, NFPA 16; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

9. *Standard for Dry Chemical Extinguishing Systems*, NFPA 17; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

E. § 1910.161. *Fixed extinguishing systems—dry chemical:*

1. *Standard for Dry Chemical Extinguishing Systems*, NFPA 17; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *National Electrical Code*, NFPA 70; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Standard for the Installation of Equipment for the Removal of Smoke and Grease-Laden Vapor from Commercial Cooking Equipment*, NFPA 96; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

F. § 1910.162. *Fixed extinguishing systems—gaseous agents:*

1. *Standard on Carbon Dioxide Extinguishing Systems*, NFPA 12; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *Standard on Halon 1301*, NFPA 12B; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Standard on Halon 1211*, NFPA 12B; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. *Standard on Explosion Prevention Systems*, NFPA 69; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. *National Electrical Code*, NFPA 70; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. *Standard on Automatic Fire Detectors*, NFPA 72E; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

7. *Determination of Halon 1301/1211 Threshold Extinguishing Concentrations Using the Cup Burner Method*; Riley and Olson, Ansul Report AL-530-A.

G. § 1910.163. *Fixed extinguishing systems—water spray and foam agents:*

1. *Standard for Foam Extinguisher Systems*, NFPA 11; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *Standard for High Expansion Foam Systems*, NFPA 11A; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Standard for Water Spray Fixed Systems for Fire Protection*, NFPA 15; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. *Standard for the Installation of Foam-Water Sprinkler Systems and Foam-Water Spray Systems*, NFPA 16; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

H. § 1910.164. *Fire detection systems:*

1. *National Electrical Code*, NFPA 70; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *Standard for Central Station Signaling Systems*, NFPA 71; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Standard on Automatic fire Detectors*, NFPA 72E; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

I. § 1910.164a. *Employee alarm systems:*

1. *National Electrical Code*, NFPA 70; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *Standard for Central Station Signaling Systems*, NFPA 71; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Standard for Local Protective Signaling Systems*, NFPA 72A; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. *Standard for Auxiliary Protective Signaling Systems*, NFPA 72B; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. *Standard for Remote Station Protective Signaling Systems*, NFPA 72C; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. *Standard for Proprietary Protective Signaling systems*, NFPA 72D; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

J. § 1910.165. *Fire brigades:*

1. *Private Fire Brigades*, NFPA 27; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

2. *Initial Fire Attack, Training Standard On*, NFPA 197; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

3. *Fire Fighter Professional Qualifications*, NFPA 1001; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

4. *Organization for Fire Services*, NFPA 1201; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

5. *Organization of a Fire Department*, NFPA 1202; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

6. *Protective Clothing for Structural Fire Fighting*, NFPA 1971; National Fire Protection Association, 470 Atlantic Avenue, Boston, MA 02210.

7. *American National Standard for Men's Safety-Toe Footwear*, ANSI Z41.1; American National Standards Institute, New York, NY 10018.

8. *American National Standard for Occupational and Educational Eye and Face Protection*, ANSI Z87.1; American National Standards Institute, New York, NY 10018.

9. *American National Standard, Safety Requirements for Industrial Head Protection*, ANSI Z89.1; American National Standards Institute, New York, NY 10018.

10. *Specifications for Protective Headgear for Vehicular Users*, ANSI Z90.1; American National Standards Institute, New York, NY 10018.

11. *Testing Physical fitness*; Davis and Santa Maria. *Fire Command*, April 1975.

12. *Development of a Job-Related Physical Performance Examination for Fire Fighters*; Dotson and Others. A summary report to the National Fire Prevention and Control Administration. Washington, DC. March 1977.

13. *Proposed Sample Standards for Fire Fighters' Protective Clothing and Equipment*; International Association of Fire Fighters, Washington, DC.

14. *A Study of Facepiece Leakage of Self-Contained Breathing Apparatus by DOP Man Tests*; Los Alamos Scientific Laboratory, Los Alamos, NM.

15. *The Development of Criteria for Fire Fighters' Gloves*; Vol. II: *Glove Criteria and Test Methods*; National Institute for Occupational Safety and Health, Cincinnati, OH. 1976.

16. *Model Performance Criteria for Structural Fire Fighters' Helmets*; National Fire Prevention and Control Administration, Washington, DC. 1977.

17. *Firefighters: Job Safety and Health Magazine*, Occupational Safety and Health Administration, Washington, DC. June 1978.

18. *Eating Smoke—The Dispensable Diet*; Utech, H.P. *The Fire Independent*, 1975.

19. *Project Monoxide—A Medical Study of an Occupational Hazard of Fire Fighters*; International Association of Fire Fighters, Washington, DC.

20. *Occupational Exposures to Carbon Monoxide in Baltimore Firefighters*; Radford and Levine. Johns Hopkins University, Baltimore, MD. *Journal of Occupational Medicine*, September 1976.

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FRIDAY, DECEMBER 22, 1978

PART VI



**DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE**

**National Institutes of
Health**



**RECOMBINANT DNA
RESEARCH**

Revised Guidelines

revised
draft

[4110-08-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

RECOMBINANT DNA RESEARCH

Revised Guidelines

I am announcing today several actions affecting the conduct of recombinant DNA research in this country.

In taking these steps, I have been guided by my responsibility to allow the maximum freedom of scientific inquiry consistent with the protection of the public health and the environment and with respect for the important ethical concerns surrounding genetic research in general.

The research techniques used to produce recombinant molecules of deoxyribonucleic acid, the complex chemical that codes genetic information for all living cells, hold great promise for significantly advancing our understanding of fundamental biological processes. Moreover, this research may also hold potential for the commercial production of needed biological materials and agricultural products.

From the pioneering days of this research, many of this nation's leading scientists expressed concern that the insertion of foreign genes into microorganisms could carry the potential for harm by yielding new disease-producing organisms. Although no harm has resulted from recombinant DNA research to date, there has been widespread uncertainty as to the degree of risk involved.

We must always recognize that scientific knowledge is not immutable; it is constantly changing as research generates additional information and understanding. Public policy in the field of science must therefore be flexible—to allow change as knowledge and understanding increase. The requirements that we impose must constantly be revised and updated to reflect new knowledge. Today the experience and insights that we have gained provide the basis for relaxing some of the restrictions the National Institutes of Health first imposed in 1976 on recombinant DNA research it funds.

The actions I am announcing today strive to allow the greatest freedom of scientific inquiry possible. At the same time, they provide the protections necessary to safeguard the public health and environment and also provide the opportunity for those concerned to raise any ethical issues posed by recombinant DNA research.

Specifically, I am today:

• Approving final guidelines prepared by the National Institutes of Health that significantly revise the

safety requirements for conducting recombinant DNA research;

• Taking immediate steps to require that research conducted by private companies complies with the NIH guidelines, primarily through use of the regulatory authority of the Food and Drug Administration (at Appendix A);

• Requesting the Environmental Protection Agency to review its authority and to take all action it can to require compliance with the NIH guidelines by companies that carry out DNA research but whose products are not regulated by the Food and Drug Administration;

• Directing NIH to increase its research designed to determine the extent of risk associated with recombinant DNA research (at Appendix B);

• Broadening substantially the public representation on the HEW advisory committee that will assist NIH in administering the revised guidelines;

• Increasing significantly public access to information about recombinant DNA research activities and increasing public participation in the administration of the guidelines in local communities.

REVISED GUIDELINES

The revised final guidelines that NIH has developed and that I am approving today set new directions for regulation of future recombinant DNA research. These final guidelines retain much of the guidelines that NIH published in proposed form last July. But NIH has made many revisions based on public comment and on the review conducted by a Departmental committee. The Director, NIH, has prepared a Decision Document responding to the public comments and explaining the reasons for the revision.

The final guidelines relax some of the restrictions under which recombinant DNA research has been conducted since 1976, and at the same time increase the role of the public in approving and monitoring recombinant DNA experiments.

In particular, these final guidelines relax in two major respects the guidelines that were placed in effect in 1976.

• *The revisions exempt altogether five categories of experiments from the guidelines' restrictions.* NIH has concluded that these experiments present no known health risk. Approximately one-third of research covered under the existing guidelines would be exempted under the revised standards.

The revised guidelines continue to ban all six categories of potentially hazardous research that the 1976 guidelines prohibited. They will now, however, permit the Director of NIH to grant—following public notice and

comment—case-by-case exceptions to these prohibitions with appropriate safeguards.

• *The revised guidelines will ease restrictions on other permissible experiments.* Depending on the potential risk of an experiment, both the 1976 guidelines and today's revised guidelines require a researcher to comply with one of four levels of protective laboratory procedures and one of three levels of restrictions on the type of organism that may be used in the research. The revised guidelines assign almost all categories of research physical containment and/or biological containment levels at least one step lower than in the 1976 guidelines. Since the likelihood of harm now appears more remote than was once anticipated, the scientific community has now concluded that this downgrading is appropriate. The four levels of physical containment and three levels of "biological containment"—the use of weakened organisms that cannot survive outside the laboratory—set by the 1976 guidelines would remain the same.

Based on the review and public hearing conducted by a Departmental committee, the guidelines have been significantly rewritten from the July version to increase public participation at both the local and national level:

• *Twenty percent of the members of local Institutional Biosafety Committees (IBC's) must represent the general public, and have no connection to the institution.* The 1976 guidelines had no such requirements for public participation.

• *Important records must be made public.* The bulk of IBC records must be made available to the public and problems, violations, illnesses and accidents must be reported to NIH.

• *At the national level, major actions cannot be taken without advice of the Recombinant DNA Advisory Committee (RAC) with public and Federal agency comment.* Major actions include decisions to approve on a case-by-case basis experiments that are generally prohibited, to exempt additional categories of research from the guidelines, to permit the insertion of genes in new types of bacteria, and to approve changes in the guidelines themselves.

Finally, today's revised guidelines provide more explicit guidance both for local institutions and for NIH to follow in implementing the guidelines.

• *Institutions must develop emergency plans covering accidental spills and personnel contamination; health surveillance programs for projects needing such safeguards; and training programs for IBC members, researchers, and other laboratory staff.*

• *Under the revised guidelines, the NIH Director cannot approve pro-*

posed actions unless he determines that they present no significant risk to health or the environment.

GUIDELINE COVERAGE

The revised guidelines apply to all recombinant DNA research conducted at any institution which receives NIH funds for recombinant DNA research. At these institutions, even research conducted without NIH support must comply with the guidelines. Other research agencies of the Federal government have assured us that they will require compliance with the NIH guidelines for all recombinant DNA research that they conduct or support.

We are also taking action to assure that the guidelines apply, to the greatest extent possible, to research conducted in the private sector.

● At my direction, the Food and Drug Administration is today announcing its intent to propose than any recombinant DNA research submitted to satisfy FDA's regulatory requirements must have been conducted in compliance with the NIH guidelines.

● I have also written to Douglas Costle, the Administrator of the Environmental Protection Agency (EPA) and asked him to review EPA's regulatory authority to determine whether EPA can regulate recombinant DNA research conducted privately that is not submitted to the FDA. I have asked him to take all action he can.

If both FDA and EPA act to regulate privately conducted recombinant DNA research, virtually all recombinant DNA research in this country would be brought under the requirements of the revised guidelines.

BROADENED COMMITTEE MEMBERSHIP

I will announce shortly the names of 14 new members of HEW's recombinant DNA Advisory Committee. In addition to scientists who are experts in molecular biology and other disciplines, the Committee will be expanded to include persons knowledgeable in a wide variety of fields such as law, public policy, ethics, the environment and public health. The Committee will serve as the principal advisory body to the Director of NIH and to the Secretary of HEW on recombinant DNA policy.

INCREASED RISK ASSESSMENT RESEARCH

While our knowledge about the risks of recombinant DNA has increased dramatically, much remains unknown. The scientific community must continue to assess the extent of the risks posed by recombinant DNA research. I am therefore directing the Assistant Secretary for Health and the Director of the National Institutes of Health to formulate a plan for carrying out a balanced program of additional risk

assessment experiments. In my view, the more risk assessment experiments NIH conducts or supports, the better we can judge whether the guidelines—and actions taken under them—afford appropriate protection for health and the environment.

Today's action represents the culmination of a long and thorough process that has sought at each step to balance the important concerns involved in recombinant DNA research. The National Institutes of Health in 1976 published guidelines to govern research which it funds.

The 1976 guidelines:

● Prohibited six categories of recombinant DNA experiments which experts felt posed significant hazards.

● Defined degrees of physical and biological containment necessary to prevent recombinant DNA organisms from escaping into the environment and surviving.

● Described permissible categories of recombinant DNA research and assigned levels of physical and biological containment for each.

● Described specific roles and responsibilities for principal investigators, research institutions, institutional biohazard committees, and the NIH.

Since issuance of the 1976 guidelines, recombinant DNA techniques have become much more widely used in research, and more has been learned about the limits of potential risks in using this technology.

In light of this new knowledge, the Director, NIH, on July 28, 1978 proposed substantial modification and relaxation of the guidelines. At that time, I named a Departmental review committee consisting of Peter Libassi, the Department's General Counsel, as Chairperson; Dr. Donald Fredrickson, the Director of NIH, as Vice Chairperson; Dr. Julius Richmond, Assistant Secretary for Health; and Dr. Henry Aaron, then Assistant Secretary for Planning and Evaluation. I asked the Committee to examine the proposed guidelines and to hold a public hearing on the guidelines.

In reviewing the guidelines, the committee solicited and heard comments from representatives of environmental groups, unions, pharmaceutical companies, institutional biosafety committees and Congressional staff members. The committee reviewed more than 170 letters from the public commenting on the revisions. The committee played a vital role in the process which led to the revised guidelines and unanimously recommended that the revised guidelines be approved.

These revised guidelines provide for a flexible, open system that can accommodate new scientific information that may warrant change, either to relax or to increase safety requirements.

I applaud all who have labored to develop these guidelines: The scientific community, the public, and workers at the Federal, State and local levels. This research holds promise for adding to our understanding about basic biological processes. These guidelines should permit that promise to be realized without presenting any significant risk to public health or the environment.

Dated: December 15, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

APPENDIX A

THE SECRETARY OF HEALTH,
EDUCATION, AND WELFARE,
Washington, D.C. 20201.

DECEMBER 15, 1978.

MEMORANDUM TO: Commissioner of Food and Drugs, Director, National Institutes of Health.

THROUGH: Assistant Secretary for Health.

SUBJECT: FDA Requirements for Compliance with the NIH Guidelines for Recombinant DNA Research.

With my approval and that of the Assistant Secretary for Health, the Director of the National Institutes of Health is issuing today revised Guidelines for Recombinant DNA Research.

These Guidelines set down requirements for all recombinant DNA research either conducted by NIH or conducted by institutions receiving NIH funds for recombinant DNA research. Other Federal agencies funding recombinant DNA research have agreed to require recipients of their funds to comply with these Guidelines as well.

To the maximum extent possible, we should extend the coverage of the NIH Guidelines to recombinant DNA research carried out in the private sector, with appropriate protection for proprietary and patent rights.

As we discussed, the pharmaceutical industry does most of the recombinant DNA research that is carried out privately in this country. Accordingly, the Food and Drug Administration is issuing today a Notice of Intent to propose regulations. These proposed regulations would require that all recombinant DNA research submitted to the FDA to satisfy the FDA's regulatory requirements be carried out in compliance with the Guidelines. This requirement should bring under the Guidelines the vast majority of recombinant DNA research conducted in this country by the private sector. If FDA does adopt such regulations, there must be close cooperation between NIH and FDA in implementing them. With the Commissioner of Food and Drug taking the lead, you should prepare a plan of action on the steps necessary to apply the Guidelines to the private sector.

Please submit a memorandum describing your proposed plan of action at the time you submit proposed regulations.

JOSEPH A. CALIFANO, Jr.

APPENDIX B

THE SECRETARY OF HEALTH,
EDUCATION, AND WELFARE,
Washington, D.C. 20201.

DECEMBER 15, 1978.

MEMORANDUM TO: Assistant Secretary
for Health, Director, National Institutes,
National Institutes of Health.

SUBJECT: Assessing the Risk of Recombinant
DNA Research.

With the issuance today of revised Guidelines for recombinant DNA research, the responsibility of the National Institutes of Health to conduct and support experiments designed to determine the risks of recombinant DNA research becomes even more important than it has been in the past. The revised Guidelines now require a finding by the Director of NIH that each proposed action under the Guidelines "presents no significant risk to health or the environment." It is critical that these judgments, to the maximum extent possible, be based on the firm foundation of documented research that is subject to peer review.

Experience and knowledge gained from the broad range of recombinant DNA research already underway will provide much information for assessing risks. But in many areas special research and careful attention will be needed. To discharge our responsibility to assess risk before certain research is conducted on a wide-spread basis, NIH should formulate a plan for carrying out a balanced program of more such risk-assessment experiments either at NIH directly or under NIH-supported grants or contracts. In my view, the more risk assessment experiments NIH carries out, the better we will be able to judge whether the Guidelines—and actions taken under them—afford appropriate protection for health and the environment.

Your overall plan to conduct risk assessment experiments should be published for public comment and presented for review to the Recombinant DNA Advisory Committee annually. The first such plan should be ready for publication and submission to the Advisory Committee by March 30, 1979.

JOSEPH A. CALIFANO, Jr.

NOTICE OF RELEASE OF REVISED NIH GUIDELINES FOR RECOMBINANT DNA RESEARCH

Today, the Director, National Institutes of Health, with the approval of the Assistant Secretary for Health and the Secretary of Health, Education, and Welfare, is authorizing the release of revised *NIH Guidelines for Research Involving Recombinant DNA Molecules*. The Guidelines and a Decision of the NIH Director to issue the revised guidelines are published below.

Dated: December 15, 1978.

DONALD S. FREDRICKSON,
Director,
National Institutes of Health.

DECISION OF THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, TO ISSUE RE- VISED GUIDELINES FOR RECOMBINANT DNA RESEARCH

DECEMBER 1978.

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I. SCOPE OF THE GUIDELINES

A number of commentators at the September 15 hearing and correspondents addressed issues concerning the scope of the Guidelines. Views were expressed for an against exempting experiments from the Guidelines even though some argued that the risk was minimal or nonexistent. Specific issues that were raised are discussed below.

GENERAL APPLICABILITY

Several commentators spoke to the scope of the applicability of the Guidelines. Some questioned the right of NIH to apply the Guidelines to investigations not supported by NIH at an institution that receives some NIH funding for recombinant DNA research. Others, however, urged that the scope be broadened to include all institutions receiving NIH or, indeed, DHEW funding for whatever purpose.

I addressed these concerns in my Decision accompanying the proposed revision published in the *FEDERAL REGISTER* on July 28, 1978. I noted that partial adherence to the Guidelines within an institution would defeat the purpose of extending maximal protection to the community. Thus, it would be inconsistent for NIH to provide funds for recombinant DNA activities to an institution that did not meet the standards of the Guidelines in all of its recombinant DNA research, regardless of the source of funding. This principle is sound and NIH has the authority to apply it.

Some commentators took exception to the statement in the section on General Applicability that once certain research is approved at the local level, it may proceed. Several corre-

spondents pointed out that the language conveys the sense that all recombinant DNA research can proceed solely on the basis of local approval. This is not the case and this section does not, in fact, deal appropriately with the matter. Accordingly, the topic has been deleted from the Applicability section and dealt with extensively in part IV of the Guidelines and in the Administrative Practices Supplement.

Another commentator urged that the requirements of the Guidelines be extended to NIH-supported research in foreign countries. The proposed revised Guidelines (PRG) state that the Guidelines are applicable, but if the host country has rules for the conduct of recombinant DNA projects, then a certificate of compliance with those rules may be submitted to NIH in lieu of compliance with the NIH Guidelines, so long as the safety practices of the two are reasonably consistent. Of course, in countries with no guidelines, the NIH Guidelines must apply to NIH-supported research.

PROHIBITIONS AND EXEMPTIONS— GENERAL COMMENTS

There were a large number of comments on prohibitions, exceptions to prohibitions, and exemptions from the Guidelines. There was some confusion on the difference between exceptions and exemptions. Experiments excepted from the prohibitions are assigned appropriate containment levels and thus must be conducted in compliance with the Guidelines. For experiments under the exemptions (and not affected by prohibitions), the Guidelines do not apply at all.

Several of the commentators spoke to one or more of the criteria used for exempting experiments from the Guidelines. Some said that the criterion for granting exemptions should be safety and not whether DNA exchange occurs in nature. This issue is discussed in the Environmental Impact Assessment accompanying the revised Guidelines in the *FEDERAL REGISTER* of July 28, 1978.

It was noted there that, according to some commentators, safety rather than "novelty" should be the criterion for exclusion. That is, any recombinant molecule that poses a potential threat to the public health or the environment should be covered by the Guidelines regardless of whether the molecule is a novel one. An opposing view, expressed by other commentators, was that a proper criterion should be whether the potential hazard of the recombinant molecule would differ significantly from the biohazard posed by a molecule already found in nature or from a biohazard that can be successfully handled by conventional methods. It proved impossible to reconcile these differences of opinion in the definition itself, and

so the Exemptions sections was developed.

In my view, the criteria given in the exemptions and prohibitions sections of the PRG defining recombinations similar to natural events are both conservative and reasonable. It should be noted that the wording of prohibition I-D-5, "that are not known to acquire it naturally," is identical to that of the original 1976 Guidelines.

PROHIBITIONS—SPECIFIC COMMENTS

Several commentators requested clarification of prohibition I-D-2 concerning the deliberate formation of potent toxins. Was it intended to cover only toxins for vertebrates or those for all species? A commentator noted that fungi produce antibiotics that are potent toxins for bacteria. It is not the intent of this prohibition to cover such toxins but only potent toxins for vertebrates. Accordingly, new language makes it clear that "potent toxins" refers specifically to vertebrates.

A number of commentators from the agricultural community urged that mechanisms be set in place for waiver of prohibition I-D-4, which bans deliberate release into the environment of any organism containing recombinant DNA. Recognizing the need expressed by these commentators for more definitive standards for allowing exceptions, I will refer the matter to the Recombinant Advisory Committee (RAC) for its consideration. Indeed, in response to several suggestions from commentators, the RAC will be asked to address conditions under which exceptions to various prohibited categories of experiments may be granted.

Another commentator urged that for waiver of the prohibition on deliberate release into the environment, the Guidelines explicitly require compliance with the National Environmental Policy Act (NEPA) and any additional safeguards to be stipulated by EPA. Others urged that full Environmental Impact Statements be filed on most exceptions to the prohibitions. As I noted in my Decision accompanying the PRG on July 28, 1978, all waiver decisions will include a careful consideration of the potential environmental impact. Some decisions may be accompanied by a formal assessment or statement—a determination, however, that can only be made on a case-by-case basis. In the new procedures for the Federal agencies under the Guidelines, all agencies represented on the Federal Interagency Committee, including EPA and OSHA, will have nonvoting members on the RAC, and will thus have opportunity to participate in all the RAC's deliberations. In addition, the Federal Interagency Committee may be convened to discuss issues its members believe are important prior to the granting of any

waiver. Exceptions to prohibitions also fall under the procedure described in Section IV-E-1-b-(1) of the Guidelines that involves at least 30 days of public comment.

The standard for exceptions to prohibitions in the Guidelines was a source of much comment. Some commentators believe that the standard should be "no significant risk and a clear social benefit to be realized." Others urged that exception to the prohibitions be justified only to permit special risk-assessment experiments. I believe that Section IV-E-1-b sets the appropriate standard at this time. This is particularly so in light of the new procedural protections described in part IV requiring public and Federal agency participation in such decisions.

There were a number of comments from the private sector concerning the prohibition on large-scale experiments (I-D-6). They noted that the necessity for conducting scale-up experiments (greater than 10-liter volumes) is imminent, and that, in their view, such experiments present no unusual hazards. I recognize the need for conducting experiments with more than 10 liters of culture and the extensive experience of industry in dealing with larger volumes. The criteria set forth in the Guidelines make the prohibition inapplicable when the recombinant DNAs are rigorously characterized and free of harmful DNA sequences. An exception to the prohibition may also be granted [see Guidelines, Section IV-E-1-b-(1)-(e)] and the RAC will begin to consider specific standards for exceptions.

EXEMPTIONS—SPECIFIC COMMENTS

In the PRG all of the prohibitions overrode the exemptions. There were suggestions that certain prohibitions not apply to the exemptions. It was recommended, for example, that the prohibitions relating to the deliberate release of recombinants into the environment and the deliberate transfer of drug resistance not apply to exempt experiments. In my view these prohibitions must continue to apply for the present.

It was also argued that the prohibition on large-scale experiments should not apply to exempt experiments. This prohibition, indeed, is different from the other five, as is explicitly noted in the 1976 Guidelines. In the PRG the language was tightened: "recombinant DNAs known to make harmful products" was changed to "unless the recombinant DNAs are rigorously characterized and are shown to be free of harmful genes." For experiments in the exempt category that call for more than 10 liters of culture, it seems unnecessary to have the recombinant DNAs meet these criteria. Therefore, a

fixed prohibition, unduly restrictive in these cases, no longer applies, and experiments which meet the criteria of the exemptions may be conducted in volumes of over 10 liters. The first five prohibitions continue to apply to all experiments and override the exemptions.

A correspondent stated that the inclusion of specific exemptions in the Guidelines is premature. It was recommended that exemptions be granted instead on a case-by-case basis after risk-assessment, NEPA compliance, public participation, and a finding based on experimental data that the exemption presents no significant risk to health or the environment. In my view the five classes of exemption listed in the PRG, as discussed in the accompanying Decision Document and Environmental Impact Assessment, are warranted. It is a view shared by the RAC and many commentators throughout this long period of proposed Guideline revision. All of the participants and observers concerned with the Guidelines will benefit from disengagement of the least potentially hazardous use of recombinant DNA techniques, so that attention may be focused on the areas still encompassed by the Guidelines.

A witness at the September 15 hearing objected to exemption of experiments involving naked DNA, maintaining that the Rowe-Martin experiment showed that the ingestion of naked polyoma DNA by mice resulted in infection. This is incorrect. In that experiment the DNA caused infection in mice only when injected, and then with much reduced ability as compared with the whole virus. It is a common experience that naked DNA molecules are fragile and difficult to retain intact in the laboratory. Ingested DNA would be destroyed in the alimentary tract by stomach acid and the various enzymes that degrade DNA. The one route whereby naked DNA molecules might be hazardous is accidental injection, as into a laboratory worker. The same could be said for many of the chemicals used in experiments. For this reason, the use of hypodermic needles in laboratory procedures is avoided whenever possible. Their use is specifically discouraged in the section of the Guidelines on Containment. Further, Footnote 5 has now been expanded to recommend inactivation of DNA before disposal, and specifically refers to the Laboratory Safety Monograph as a source of advice on acceptable methods.

A commentator on behalf of the RAC's Working Group on Prokaryotic Host-Vectors Other than *E. Coli* K-12 proposed modification of Exemption I-E-3. He provided the following justification: "Addition of the proposed clause I'or which have been trans-

ferred to another host by known physiologic means"] will exempt the following types of experiments:

"An *E. coli* strain is constructed in which a chromosomal gene of *E. coli* has been enzymatically joined to plasmid DNA; this plasmid is then transferred by conjugation into another bacterial host that is not on the Director's List of bacteria that exchange with *E. coli*.

"It seems logical that this experiment should be exempt, because it involves natural genetic exchange between two organisms both of which are exempt. The *E. coli* donor is exempt because it represents a gene combination that could easily arise by natural means. As the transfer can also occur naturally, the same statement applies also to the second host carrying the plasmid.

"If unidirectional plasmid transfer had been accepted as an adequate criterion for inclusion on the Director's List, the strain would be automatically exempt. The reason for not accepting this criterion was that some doubts had been expressed as to whether unidirectional plasmid transfer automatically implied bidirectional transfer of chromosomal genes. However, in the present case, the ability to construct the desired recombinant is *de facto* evidence that it could arise by natural means.

"A specific proposal was submitted to RAC *** to splice an *E. coli* suppressor into an *E. coli* transposon, then move the resulting combination into *Myxococcus* by P1 transduction. This strategy will allow the isolation of suppressible mutants of *myxococcus* and its phages, which will greatly expedite genetic studies of development and motility in that organism."

The change as proposed by the commentator is warranted in my view, and has been made, with minor rewording for clarity.

There were many comments concerning the list of exchangers in Appendix A to be exempt from the Guidelines under exemption I-E-4.

Many commentators urged more explicit standards for inclusion on the list. As discussed in detail in the section of this document dealing with Appendix A, the criteria for inclusion on the list have been tightened and made more explicit, reducing the list considerably and thus exempting fewer experiments from the Guidelines.

II. CONTAINMENT

The object of the containment provisions of the proposed revised Guidelines is to ensure that experimental DNA recombination will have no ill effects on the researchers, the general public, or the environment. Public comments on part II of the Guidelines and on the Laboratory Safety Mono-

graph were generally supportive. However, a number of pertinent issues relating to physical and biological containment were raised in correspondence and at the public hearing held on September 15, 1978. They deserve consideration and are addressed below.

PHYSICAL CONTAINMENT

Effectiveness of Physical Containment

One commentator observed that laboratories cannot provide foolproof containment of dangerous organisms and that a biohazard outbreak can rapidly spread to virtually any neighborhood on earth. He cited the recent laboratory accident in England attributed to the escape of a smallpox virus through a faulty filter. NIH agrees that when known hazardous agents are dealt with, the risk of a laboratory-acquired infection cannot be totally eliminated. I believe, however, that adherence to the Guidelines provides ample protection for laboratory personnel, the public, and the environment. Even if an organism should escape from the laboratory, the mutational changes underlying "biological containment" would greatly decrease the probability that it would survive in the environment. The recent incident in England involves an extraordinarily hardy, resistant, and virulent organism to which man is very susceptible—one that is hardly comparable to weakened strains of *E. coli* generally used in recombinant DNA research or to the new host-vector (HV) systems now under consideration.

Laboratory Practices

A correspondent noted that persons on antibiotics or immunosuppressive drugs, or those with open lacerations or chronic digestive abnormalities, are not prohibited from entering the laboratory under any of the physical containment levels. In response, it should be pointed out that the *Laboratory Safety Monograph* (LSM), page 204, provides that "laboratory workers who are undergoing treatment with steroids, immunosuppressive drugs or antibiotics, or are suffering from colitis, ileitis, active chronic diarrhea, or other gastrointestinal disorders, should have a medical evaluation to determine whether they should be engaged in research with potentially hazardous organisms during the time of their illness." Reference to this now appears in Section IV-D-1-h, which also mandates that the institution shall provide health surveillance of laboratory personnel.

Several commentators noted that absence of specific guidance for the rodent and insect control programs required in Section II-B-1-a-(9), II-B-2-a-(12), II-B-3-a-(12), II-B-4-a-(16). The large variety of situations and animal involved makes precise speci-

cations impractical. It is the intent of the Guidelines, however, that adequate attention be paid to this problem, and further guidance will be provided in the next edition of the LSM.

Emergency Procedures

One commentator urged that the Guidelines include specifications for cleanup procedures to be followed in the event of a spill or accidental release of organisms into the environment. A witness recommends that for prompt and adequate response to emergencies, a team of experts from NIH and CDC be formed, and that their names and telephone numbers be published for easy access. Emergency procedures are currently detailed in the LSM, pp. 194-195. These will be expanded in the next edition of the monograph to provide for an NIH-CDC emergency consultation and response program to assist institutions in managing serious accidents. Twenty-four-hour telephone coverage will afford an immediate response capability.

One correspondent recommended that all bacteria used in recombinant DNA experiments be tagged so that their spread, in the event of an accident, could be detected in the environment. A general requirement to this effect is not now practicable. It should be noted, however, that in many cases bacteria are tagged to permit identification.

A correspondent raised the prospect that P2 and P3 containment facilities could be compromised by an earthquake. Most institutions have emergency plans for dealing with natural disasters. Selected references are cited in the LSM. If necessary, NIH and CDC are available to provide direct assistance in the management of specific emergency situations. Moreover, institutions in areas subject to natural disasters such as earthquake must generally conform to building code requirements that are designed to minimize the effects of such disasters.

Issues Related to Specific Containment Levels

A number of additional comments were received from public commentators relating to the proposed actions at specific levels of physical containment.

One correspondent said that the new P1 and P2 containment conditions are not significantly different, and that the difference between P1 and P2 should be approximately the same as that between HV1 and HV2. He objected strongly to the escalation of the P1 and P2 containment rules.

NIH believes that the differences between the two levels of containment are significant. For example, P2 requires use of biological safety cabinets to contain aerosol-producing equipment, use of the universal biohazard

sign, and use of gowns, coats, and uniforms. It limits entry into a laboratory to those who have been specifically informed advised of the nature of the research being conducted.

In response to a witness who averred that P1 actually represents no containment, it can be noted that P1 is the equivalent of the physical-containment level used in medical microbiological and hospital diagnostic laboratories throughout the world for handling infectious organisms. Indeed, it was suggested that a need exists for an even lower level of physical containment than P1 (for organisms considered of minimal risk). I do not believe it prudent, however, to permit a lower level of containment for experiments covered by the Guidelines.

In the *Decision of the Director* published with the NIH-proposed revised Guidelines on July 28, 1978, I indicated that mouth-pipetting would no longer be permitted in P1 containment. Since it is already prohibited in P2 through P4 containment, this would ban the use of mouth-pipetting for any experiment covered by the Guidelines. One commentator feels that mouth-pipetting should not be prohibited under P2 conditions and should definitely be allowed under P1 containment because of its superior efficiency. The banning of mouth-pipetting at the P1 level, however is in accord with the advice of safety experts; the present availability of excellent mechanical devices for pipetting makes the alternative, in my opinion, a practicable one.

A correspondent suggested that use of biohazard signs at the P2 level of containment should be discontinued: "They should be reserved for demonstrated biological hazards. There is a real danger that overuse of these signs in cases where workers know they do not apply will lead to the ignoring of all biohazard signs." While I recognize the concern expressed, I feel it prudent to require the universal sign at the P2 level when recombinant DNA materials are being handled.

For the P3 level of containment, one commentator suggested that an autoclave be within the controlled laboratory area, if not the laboratory itself, rather than merely in the same building. Another commentator makes a similar point for the P2 level. This issue was raised in comments on the revision of the Guidelines proposed by the Recombinant DNA Advisory Committee (PRG-RAC, *FEDERAL REGISTER*, September 27, 1977). As stated in my *Decision* (*FEDERAL REGISTER*, July 28, 1978), "... an absolute requirement that the autoclave must be within the controlled area is not considered appropriate, since contaminated material can be safely transported. Such a requirement would exclude the use of

autoclaves in waste-staging areas that have been conveniently sited to support an entire facility."

A commentator questions for entrance of children into P3 facilities. After considering this issue, I have decided to (1) retain the stipulation that persons under 18 years of age shall not enter a P4 facility, (2) raise the age limit for entry to P3 laboratories from 12 to 16 years of age, and (3) eliminate the age stipulation for P2 laboratories.

A recommendation that the use of a separate centrifuge room or cubicle be provided in a P3 facility to contain spills occasioned by rotor failure has not been accepted. All rooms in the P3 facility must be capable of being sealed to facilitate space decontamination. Modern centrifuges do not present the potential hazard associated with earlier models. Rotor design, operation requirements, the design integrity of the centrifuge well, and the availability of sealed centrifuge cups adequately control the aerosol hazard associated with centrifuging.

Other concerns relating to the P3 level of physical containment have been considered:

- Section II-B-3-c-(7), dealing with ventilation, has been completely rewritten to clarify the intent to permit recirculation of HEPA-filtered exhaust air.

- Section II-B-3-c-(5), which requires that laboratory doors be self-closing, has been deleted. As a correspondent observes, the Guidelines should be worded in such a way as to make facility design compatible with Section II-B-3-a-(1) requiring laboratory doors to be closed while experiments are in progress has been retained.

- A recommendation that the Guidelines be revised to require that booties be worn at all times within the P3 laboratories has not been accepted.

For the P4 level of physical containment, one correspondent would have the Guidelines specifically require the use of gloves. In response, it can be noted that most P4 experiments use Class III cabinets, which are fitted with attached arm-length rubber gloves. As shown in Table II of the PRG-NIH, however, one can work in open-faced biological safety cabinets with augmented biological containment. In this case, the requirement for gloves has now been explicitly set forth by addition of text to Table II.

In response to commentators' suggestions and NIH review, other changes have been made in the Guidelines. For example:

- Sections II-B-1-a-(5), II-B-2-a-(5), and II-B-3-a-(5) have been changed to indicate that eating, drinking, smoking, and storage of foods are not permitted in the "laboratory area

in which recombinant DNA materials are handled."

- Sections II-B-2-a-(10) and II-B-3-a-(11) have been changed to mandate the posting of the universal biohazard sign on freezers and refrigerators "or other units" used to store organisms containing recombinant DNA molecules. In addition, the requirement for identifying storage units within the P4 facility with the universal biohazard sign has been included in Section II-B-4-a-(15).

- Additional language to clarify the use of the terms "sterilized" and "decontaminated" has been added to Sections II-B-1-a-(3), II-B-2-a-(3), II-B-3-a-(3), II-B-3-a-(8), II-B-4-a-(9), and II-B-4-a-(10).

- The requirement that the laboratory be kept neat and clean has been added to P1; it was already present at P2, P3, and P4.

- A new Section II-B-4-(18) has been added concerning vacuum outlets in the P4 facility.

SHIPMENT

New language to clarify the intent of Section II-C relating to shipment has been suggested by the Department of Transportation. This language has been incorporated (with minor modifications) into the Guidelines. The suggestion of one correspondent that certain clones be exempt from these requirements has not been accepted.

BIOLOGICAL CONTAINMENT

Certification of Host-Vector Systems

Most comments on the biological containment provisions of the proposed revised Guidelines related to development, review, and approval of host-vector (HV) systems other than *E. coli* K-12. In particular, commentators from the scientific community continue to urge development of such alternate systems. Thus, one correspondent wrote, "The anticipated potential of recombinant DNA in agriculture will be difficult, if not impossible, to realize with *E. coli* K-12 host-vector systems. Therefore, it is imperative that attention be given to the development and approval of alternate HV1 systems that may be useful in genetic engineering of plants and invertebrates." Another correspondent wrote, "While many of the regulations do not add to the safety of what are basically safe experiments, they do serve to inhibit the development of new and versatile vector systems * * *. The redundant safety testing program is too onerous, time-consuming, and in our opinion, not scientifically justified."

While I agree that research based on other host-vector systems must proceed, I believe that certification of these systems should be approached conservatively. The new systems raise

ecological and biological issues that must be carefully and thoughtfully addressed. As one correspondent cautions, "We must be very careful when, bolstered by our confidence in *E. coli* K-12 systems, we try to extrapolate to *B. subtilis*, yeast, etc." Two Working Groups of the RAC have recently met to consider alternate systems and to develop more precise and objective criteria for certification.* Many problems, however, persist for setting general standards that could be applied to all organisms. I believe that the process of review and approval described in the Guidelines will allow for full and deliberate examination on a case-by-case basis of putative HV systems and of pertinent ecological and biological issues. This process will, of course, comply fully with NEPA.

In response to one correspondent's suggestion, text has been added to Section II-D-2-a further clarifying the roles of the NIH Director and ORDA in the process of certification.

Data Required for Certification

One correspondent suggested an expansion of Section II-D-2-b-(1), relating to data to be submitted for certification of HV1 systems other than *E. coli* K-12. Specifically, he would require a thorough discussion of the physiological properties of the organism, particularly those related to its reproduction and survival and the mechanisms by which it exchanges genetic information—not simply the range of organisms with which it exchanges. I believe these characteristics to be especially crucial in approval of new systems; accordingly, Section II-D-2-b-(1) has been amended to incorporate this suggestion.

EK1 Systems

One correspondent noted that most host components of EK1 systems used in recombinant DNA research have mutations in addition to those acquired during K-12's laboratory evolution that confer special nutritional requirements, cause recombinants to be defective, or otherwise diminish survival or reduce the likelihood for transmission of recombinant DNA. It has been suggested that use of such mutations should be encouraged. In my view, much of the value of the EK1 host is its flexibility, and it does not seem necessary to explicitly recommend certain strains of *E. coli* K-12 as EK1 strains. The investigator will generally choose the more readily transformable *E. coli* K-12 strains, and many of the characteristics that enhance transformability decrease survival. In addition, by suggesting the

use of certain mutations, we may shut off research on others which might prove even more useful and safe.

FLEXIBILITY IN CHOOSING PHYSICAL AND BIOLOGICAL CONTAINMENT LEVELS

One witness and one correspondent questioned the rationale for allowing alternate levels of physical and biological containment. The concept of "flexibility" is discussed at some length in the *Decision* document, *FEDERAL REGISTER*, July 28, 1978, pp. 33052-33053, and in the accompanying *Environmental Impact Assessment*, p. 33113. Moreover, the flexibility allowed in alternate P and HV levels is carefully explained in the text of the Guidelines, and the investigator must follow the explicit requirements set forth in part III of the Guidelines and Tables I and II.

III. CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

GENERAL CONSIDERATIONS

Many of the commentators supported the levels of containment recommended for covered experiments. They concurred with the scientific arguments presented in the *Decision* document and *Environmental Impact Assessment* (issued July 28, 1978) as a rationale for lowering containment levels. Some cited the reports of the Falmouth and Ascot risk-assessment meetings as confirmatory evidence, and reiterated that *E. coli* K-12 cannot be converted into an epidemic pathogen even by the introduction of additional genes from known pathogenic strains.

Many commented favorably on specific sections of the Guidelines, such as the lowered containment levels for viral DNA. Others supported the proposed containment levels for the cloning of primate DNA. One further stated that relaxation would permit major studies to be made in locating and mapping human genes. Another noted that the proposed revisions would permit the conduct of research with plants and plant-associated microorganisms and endorsed the changes based on the Workshop on Risk Assessment of Agricultural Pathogens.

A number of commentators, while generally supportive of the changes proposed, believed the Guidelines to be still too restrictive. Some urged that they either be dispensed with entirely or, in the opinion of one commentator, be replaced with the following sentence: "It would seem prudent to conduct work with organisms containing recombinant DNA under laboratory conditions appropriate to the degree of pathogenicity of the donor organisms."

I appreciate the thoughtfulness and care that have gone into the many letters. I also acknowledge a belief that the proposed revised Guidelines represent a conservative lowering of containment based on data and analysis discussed in detail in the *Decision* document and *Environmental Impact Assessment* of July 28, 1978.

On the other hand, there were commentators and witnesses who believed the lowering of containment levels in the proposed revised Guidelines was not justified. While there was a difference of emphasis in many of the comments, there appeared to be several major concerns. I shall consider each of these in turn.

● Commentators state that "much of the evidence [that NIH cites as a basis for lowering containment] has never been published or is available only in summary form." Also that "A great deal of weight has been placed on semi-authorized reports of discussions held at closed scientific meetings, attended by a small number of selected participants." They express concern that such action by NIH has prevented the wider scientific community from critical appraisal of the data. Various of these commentators state that the results of the Falmouth conference were published only two months before the proposed revision of the Guidelines was issued, that the proceedings of the Ascot conference have not been issued, and that the results of the Rowe-Martin risk-assessment experiments have not yet been published.

The extensive proceedings of the Falmouth meeting, held in June 1977, were published in the *Journal of Infectious Diseases* in May 1978. Publication in journal form usually involves a considerable delay, even after the edited manuscript, in this case constructed of transcripts of papers and discussions edited by participants, has been completed. The moderator of the Falmouth meeting, Dr. Sherwood Gorbach, Professor of Medicine and Microbiology, Tufts University School of Medicine, summarized the outcome of the meeting in a letter to me on July 17, 1977. (This letter was published as Appendix M to the October 1977 *Environmental Impact Statement*, and was also published along with letters from other participants in the *Recombinant DNA Technical Bulletin*, Volume 1, No. 1, Fall 1977.)

The report of the Ascot meeting was published as Appendix E to the *Environmental Impact Assessment (EIA)* in the *FEDERAL REGISTER* on July 28, 1978, pp. 33159-33167, and previously in the *FEDERAL REGISTER* on March 31, 1978, pp. 13748-13755. Its introduction says, "A draft of this report was sent to the members for comment and revi-

*The Working Group on Prokaryotic Host-Vectors Other Than *E. coli* met on September 12, 1978; and the Working Group on Lower Eukaryote Host-Vector Systems met on September 16, 1978.

sion, and this final version is based on the replies of all the participants."

The report of the Virus Working Group, which considered the Ascot Report, was published as Appendix F to the EIA in the *FEDERAL REGISTER* July 28, 1978, pp. 33167-33174.

The 36 participants at the Falmouth meeting are listed in the report of the meeting (*Journal of Infectious Diseases*, Vol. 137, pp. 613-614, May 1978). Most of the participants were invited by the organizing (steering) committee for the meeting, and the members of that committee are listed on these pages. In addition to invited participants, others arrived uninvited and participated.

The participants and the reasons for holding the Ascot meeting are discussed in my Decision document (*FEDERAL REGISTER*, July 28, 1978, p. 33060) and in the EIA, p. 33159.

The participants in the Virus Working Group, which met on April 6-7, 1978, to review the report of the U.S.-EMBO Workshop, are described in the EIA. (*FEDERAL REGISTER*, July 28, 1978, p. 33167). This meeting was announced in advance in the *FEDERAL REGISTER* on March 17, 1978; it was entirely open and was attended by others than the participants.

The results of the Falmouth, Ascot, and Virus Working Group meetings were discussed at a number of meetings of the Recombinant DNA Advisory Committee (RAC), where they led to recommendations for changes in the Guidelines. All meetings of the RAC have been announced in advance in the *FEDERAL REGISTER*, have been open to the public, and have been attended by many nonmembers.

The NIH is sensitive to the need for all concerned to have access to the advisory deliberations contributing materially to the substance and use of these Guidelines. Ordinarily, such meetings will be open to the public and announced in advance in the *FEDERAL REGISTER*. We have become aware that publication in the *FEDERAL REGISTER* is not sufficient notice for many, and the *Recombinant DNA Technical Bulletin* and other media will be used whenever possible to supplement announcements of meetings and disseminate reports emanating from them. NIH will also continue its publication of all commentary, transcripts of hearings, and other materials relevant to the "public record" of deliberations on the subject of the Guidelines.

Commentators state that the absence of untoward events in five years of experiments with recombinant DNA is not a valid ground upon which to justify the lowering of containment levels.

There is some merit in this objection, but experience to date should contribute to the basis for revision of

the Guidelines. When organisms containing recombinant DNA began to be constructed in 1973, it seemed unlikely to most that hazardous organisms would be produced, yet no one knew for sure. No basis for certainty has yet arrived, but some of the fears have justifiably diminished. The results to date have revealed no major biological factor overlooked in the initial analysis that suggests the guidelines should be stricter than they are. Indeed, several separate lines of evidence indicate the probability of hazards to be even lower than originally thought. That no one has become ill is the least impressive of these. More important lines include the following:

1. Numerous analyses and newer data indicating the very low probability that *E. coli* K-12 will establish itself in the human intestinal tract, thus limiting escape of the organisms in numbers sufficient to infect other living things.

2. The now widely made observation that organisms containing recombinant DNA compete very poorly for survival as compared with organisms not containing recombinant DNA. This was an anticipated finding (see October 1977 Environmental Impact Statement) but has now been documented in various instances. It is true even under laboratory conditions designed to be optimal. Only when the growth medium for the *E. coli* cells containing recombinant DNA is specifically designed to impose selective pressure on the recombinant organisms do they outgrow "Natural" competitors. (Selective pressure could be imposed, for example, by the presence of an antibiotic to which the recombinant organisms are resistant but the natural competitors are sensitive.)

3. The repeated observation that genes of higher organisms, introduced into *E. coli* by shotgun experiments, are not generally expressed. Many of the concerns about possible hazards center on the ability of a host cell to synthesize a foreign protein that might be detrimental to an organism with which the host cell comes into contact.

One correspondent said that assigning a higher degree of containment to organisms that are phylogenetically closer to man is unjustified, with the possible exception of clones capable of harboring viral sequences. The correspondent noted that "even if the cloned DNA were highly homologous to human DNA, how is it envisioned that when carried in a bacterial host it would somehow be more dangerous to man than a non-homologous DNA?" The commentator went on to state that the "production of pharmacologically active agents will clearly not depend upon evolutionary similarity to man" and that in fact such prod-

ucts will likely be specified by lower organisms.

In responding, I must note that a primary concern in the original assignment of containment levels was the possibility that viruses capable of propagating in human tissues could contaminate the DNA. The concern is greatest when the DNA donors are primates or other mammals, and so, for these, higher containment levels are provided.

A secondary consideration involves the possibility that the recombinant DNA may itself transform the host. The likelihood of such DNA integrating into the human genome, and consequently undergoing replication and expression, is directly related to the extent of homology between the foreign and host DNAs.

Another reason for making distinctions on the basis of phylogenetic relatedness is that the more closely related the species, the more likely that polypeptide hormones or related proteins would be pharmacologically active.

A more extensive discussion of the issue of phylogenetic relatedness is given in the Environmental Impact Assessment (*FEDERAL REGISTER*, July 28, 1978, pp. 33102-33104). This matter lies in a crucial area of risk analysis and will undoubtedly continue to be subject of both further debate and improved understanding in the coming months.

Commentators discuss a number of scientific "fears where there remains reason for caution," including that the virulence of *E. coli* may be increased by recombinant DNA, that recombinant plasmids might be transferred to more virulent strains of bacteria, and that bacteria or viruses containing recombinant DNA could cause autoimmune disease.

In reply, I note that these issues are discussed extensively in the proceedings of the Falmouth Conference (*Journal of Infectious Diseases*, May 1978) and in the EIA of July 28, 1978 (*FEDERAL REGISTER*).

At the Falmouth conference, evidence was presented on the attempts to make *E. coli* K-12 pathogenic. Even the introduction of *Shigella* genes into *E. coli* by nonrecombinant DNA techniques failed to produce a pathogenic organism having any phenotype suggestive of *Shigella*. There was consensus of all participants at Falmouth that *E. coli* K-12, could not be converted into an epidemic pathogen by recombinant DNA techniques.

There are great safety differences between *E. coli* K-12, an attenuated laboratory strain, and wild-type *E. coli*, as discussed in the EIA.

For an EK2 host to be certified as such, "no more than 1 in 10⁸ host cells should be able to perpetuate a cloned

DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of the transmission of the cloned DNA fragments."

A concern expressed by the commentators is that plasmids containing recombinant DNA might be transferred to other, wild-type organisms in the gut. Some appropriate risk-assessment studies concerning this possibility are being carried out. However, the Falmouth report and tests of EK2 host-vector systems present the following data to indicate that the probability of such transfer of the plasmids is extremely low:

1. H.W. Smith, looking specifically for transfer of a conjugative plasmid from *E. coli* K-12 to normal gut flora, could find no evidence that transfer occurred (Falmouth report, pages 655-660). For biological containment to be breached, transfer of a conjugative plasmid to *E. coli* K-12 would have to occur to be followed by transfer of the poorly mobilizable recombinant plasmid from *E. coli* K-12 to other organisms. (Conjugative plasmids themselves are not allowed to be used as vectors.)

2. Gene transfer *in vivo* greatly increases with colonization by both donor and recipient organisms, and colonization by *E. coli* K-12 in general and x1776 in particular is very rare.

3. Mobilization of the plasmids used in recombinant DNA experiments is extremely low, even under optimal *in vitro* conditions.

4. Transfer of the recombinant-containing vector would require a triparental mating *in vivo*, which even under the most favorable of *in vitro* conditions is not a high-frequency event. Such transfer has not been observed *in vivo*.

5. One commentator suggests that transduction might be an important mode of gene transfer. "Generalized transduction" by phage lambda does not occur. Generalized transduction by phage P1 is a low-frequency event (less than 1/10⁶ infected organisms are transduced for a particular marker) under the very best of *in vitro* conditions.

Additional information on plasmid transfer may be found in the Environmental Impact Assessment (FEDERAL REGISTER, July 28, 1978, p. 33123) and the previous October 1977 Environmental Impact Statement, both of which consider the possibility of transfer of foreign DNA from *E. coli* K-12 as well as the ability of *E. coli* K-12 to survive and spread in nature. As noted in both these documents, the maximum probability for transmission of nonconjugative plasmid vectors from *E. coli* K-12 was estimated at "less

that 1 to 1016 K-12s surviving per day in the intestine of warm-blooded animals. The probability is even lower in sewers, sewage treatment plants, and waterways." The EIA further states that *E. coli* K-12 survives poorly and is outcompeted by wild-type enteric bacteria.

The concern expressed by the commentators about the possibility of autoimmune disease will only prove true if a series of events occurs. The very low probability of the establishment of *E. coli* K-12 containing recombinant DNA in the intestinal flora is discussed above. In addition, the inserted eukaryotic gene must be transcribed, translated, and transported to a place where it can induce an immune response. These steps are highly unlikely to occur.

RISK ASSESSMENT

NIH is supporting a number of risk-assessment activities. The Rowe-Martin polyoma experiments are discussed elsewhere in this document. In addition, intramural NIH scientists are collaborating with scientists from other institutions testing the virulence in mice of *E. coli* K-12 containing "shotgun clones" of recombinant DNA derived from other species.

A number of contractors of the National Institute of Allergy and Infectious Diseases are testing the biological containment capabilities of various derivatives of *E. coli* K-12. Some are testing the survival and capacity of plasmid and phage vectors to be transmitted to secondary bacterial hosts in the gastrointestinal tract of mice and man. Others are assessing these parameters in model sewage treatment systems and in situations simulating accidental spills and other types of accidental release of the organisms from experimental procedures.

In addition, investigators proposing systems to be certified by NIH as HV1 or HV2 must perform certain specified tests on these systems relevant to their survival and transmission properties. It is also anticipated in the event that investigators request exceptions to the prohibitions for specified clones, NIH will request substantial risk assessment experiments to be performed to evaluate claims of safety.

SPECIFIC CONCERNS

In addition to their general remarks about the experimental section of the Guidelines, many commentators raised questions about the containment levels set for specific experiments. Others suggested clarifying language for certain sections. I have taken all of these recommendations under consideration. In some instances I have concurred and the Guidelines reflect the change. In others I have decided not to act or have deferred actions pend-

ing further analysis and discussion by the Recombinant Advisory Committee. In all cases I have attempted to respond and to explain the decision.

Section III-A-1: Shotgun Experiments

Comments from respondents on this section of the Guidelines reflected diametrically opposed points of view. Some commentators questioned the rationale for lowering of containment levels for shotgun experiments.

Other correspondents took a different view and requested that NIH further reduce the containment level for shotgun experiments. One advanced the argument that "these pieces of DNA in *E. coli* cannot be more dangerous than their original source."

I have decided to retain those levels of physical and biological containment described in the proposed revised Guidelines. I believe the specified containment levels represent a prudent, albeit most conservative, response to the hypothetical hazards. Rationale for them is presented in the July 28, 1978, Decision document and Environmental Impact Assessment.

Risk analysis by NIH is continuing. One important area of analysis involves the appropriateness of higher containment levels for shotgun experiments, with the tremendous dilution of potentially harmful genes, in contrast to purified clones that have been "engineered" for efficient transcription and translation of DNA inserts.

Section III-A-1-a. Eukaryotic DNA Recombinants Including Primates, Other Mammals, and Birds

Twelve commentators, the largest number of comment on a single issue, wrote to express their views on the limitation of P2+EK2 under the proposed revised Guidelines for the cloning in *E. coli* K-12 of shotgun DNA from primates, other mammals, and birds. All requested that the option of P2+EK2 or P3+EK1 be offered.

One group argues that to restrict cloning of these classes of DNA to P2 + EK2 is inconsistent, since many viral genomes could be cloned at either P2 + EK2 or P3 + EK1. Other respondents pointed out that use of P3 + EK1 conditions would provide adequate containment and would permit the inclusion of lysogenic lambda systems, which cannot be employed in an EK2 system. One stated that propagating DNA fragments in EK1 host-vector systems permits a 5-10 times greater yield of DNA than in an EK2 system. "Thus the advantage of EK2 containment should be weighed against the necessity of handling much larger volumes of cells."

I referred this matter to the RAC at their October 30-31, 1978, meeting. The RAC advised that the phrase "or P3 + EK1" be added to Section III-A-1-a-(3) (i.e., for DNA from birds) and

this has been done. For Sections III-A-1-a-(1) and III-A-1-a-(2) (DNA from mammals), the RAC recommended addition of the phrase "or P3 + EK1 with a non-mobilizable plasmid." Because the term "non-mobilizable plasmid" is not clearly defined, I am not accepting this recommendation at present, pending further review at the next RAC meeting.

Section III-A-2-a. DNA From Virus of Eukaryotes Into E. Coli K-12

There was considerable comment about various aspects of Section III-A-2-a, extending from general concerns about the reduction of containment levels from viral inserts to detailed and specific recommendations for clarification of certain phrases.

Several correspondents objected to the general relaxation of containment levels for the cloning of viruses. One stated that although the Ascot conference concluded that "cloning of the whole or any part of a viral genome must logically be less dangerous than working with the virus," his view is just the opposite. The arguments presented by this correspondent are (1) whole virus can elicit the production of antibodies, (2) whole virus with its protein coat is subject to a biological barrier which limits infection across species lines, and (3) whole virus is eliminated from the body after infection. In the view of this correspondent, all of these protective devices are subverted by cloning viral genes in a microorganism that may become established in the intestinal tract. He is also concerned that the Guidelines are not sufficiently stringent for cloning subgenomic DNA fragments of viruses. Another respondent indicated that belief that containment experiments involving animal-cell transforming viruses were substantially reduced, based on the supposed inefficiency of infection by naked DNA. She continued by stating that the decision to lower containment did not take into account the results of the Rowe-Martin risk-assessment experiments with polyoma DNA, which showed that naked polyoma DNA when injected into the bloodstream of mice caused a low-level infection.

The recommendations of the Ascot Workshop (Appendix E to the Environmental Impact Assessment), the subsequent Working Group review (Appendix F to the EIA), and the subsequent RAC review took into account the concerns of correspondents about viral containment, but nevertheless recommended lowered containment levels based on the conclusion that cloning of viruses or their fragments in *E. coli* could be no more dangerous than working with the intact virus. The containment levels were set accordingly. The three reasons cited

above as to why the cloned virus DNA might be more dangerous than the whole virus apply only to the first infected cell. The DNA would produce disease only if it became virus and spread; thus, the situation becomes the same as the usual virus infection. This possibility was thoroughly considered at Ascot, and is in the summary report of that meeting. Also, the existence of a subgenomic fragment precludes virus production and so effectively prevents the spread of infection.

The Rowe-Martin risk-assessment experiments (still in progress) are designed to compare the infectivity of a recombinant molecule containing polyoma DNA with that of nonrecombinant polyoma DNA and of whole polyoma virus. To date, there are no data available from these experiments which would lead me in any way to revise the judgements of the meetings cited above.

In response to the concern expressed about naked DNA, there is a significant difference in level of infectivity between naked DNA and whole virus particles; naked DNA is much less infectious than the virus. For additional discussion of naked DNA, see part I of this document.

A correspondent stated that there should be some definition as to whether a DNA virus is a transforming or nontransforming virus. To clarify this, a new footnote (37A) has been added to Section III-A-2-a-(1)-(b).

A correspondent pointed out that there are places in Section III-A-2-a where the word "purified" appears without referencing to Footnote 38. This has now been corrected by inserting reference to Footnote 38 where necessary, and inserting the phrase "subgenomic segments that have not been purified to the extent required in Footnote 38" at other places.

A correspondent discussed "EK1CV," defined in Footnote 40 as the "the use of an EK1 host and a vector certified for use in an EK2 system." He points out that certain EK1CV systems provided containment comparable or almost comparable to EK2, while others are only slightly better than EK1. This is true. However, in all cases the level of containment is higher than EK1. The cases in the Guidelines where EK1CV containment is specified as an option were so recommended by the RAC on the basis of the recommendation of the April 6-7, 1978, Virus Working Group (Appendix F to July 28, 1978, Environmental Impact Assessment).

Section III-A-3. Lowering of Containment for Characterized or Purified DNA Preparations and Clones

As in many other sections of the Guidelines, commentators have ex-

pressed their opinions in both general and specific terms. A commentator states that there is no information at present to "show any hazard deriving from recombinant DNA or organisms harboring such DNA * * *". In particular, it would seem quite clear that characterized cloned eukaryotic DNA elements in *E. coli* pose no conceivable hazard." Pursuing this line of reasoning, the commentator argues for elimination of regulation and, in particular, suggests that "consideration be given to a change in the Guidelines so that institutional biohazard committees could be empowered to exempt characterization clones from further regulation."

The proposed revisions in the Guidelines empower the IBCs to give approval for a single-step reduction in physical or biological containment upon receipt of evidence of characterization of a clone and its freedom from harmful genes. Further reductions, or cases involving primate DNA or lowering of containment levels below P1 + EK1, require prior approval by NIH. I do not believe it prudent to accept the commentator's recommendation at this time.

Two comments were received on the criteria for the terms "purity" and "free from harmful genes." Once commentator expressed concern over the inadequate definition of these terms. He believes they are not defined with sufficient precision to guarantee uniform decisions, particularly when the authority to lower containment by one step is left with the IBC. The commentator suggests more rigorous criteria for purity (other than 99 percent) and a broader definition of "harmful gene" to include the concept "that genes which might not be harmful when expressed in their original organism could indeed be harmful if expressed out of context in an unrelated organism."

The other correspondent discussed Footnote 41 which requires that the "desired DNA represents at least 99 percent (w/w) of the total DNA in the preparation" before it may be considered "purified." He stated: "Its adoption reflected the supercautious mood prevalent at that time rather than a clear-cut scientific judgement. In my view, requiring that a DNA fragment should be 90-95% pure (as judged by at least two different analytical procedures) to remove it from the shotgun classification is more realistic and no less safe. Requiring that a DNA fragment be >99 % pure prior to cloning asks for the most stringent and detailed documentation without any real advantage."

The term "purity" is very explicitly defined in Footnote 41. The requirement is that the desired DNA must represent at least 99 percent (w/w) of

the total DNA in the preparation. In addition, at least two biochemical or physical procedures are required for verification of purity.

Footnote 3 gives guidance to the IBCs on many factors to be considered before deciding that DNA recombinants are "free of harmful genes." Further specificity seems unwarranted. I believe that to broaden the definition to include the concept of "harmful" when a gene is expressed out of the normal physiological context would be contrary to the intent of Footnote 3. In considering this issue, I have noted that in the proposed revised Guidelines, different terms are used: i.e., in Section III-A-3, "and the absence of harmful genes established"; in Section III-A-3-a, "are free of harmful genes"; in section III-A-3-b, "and there is sufficient evidence that it is free of harmful genes." These have all been changed (also in Footnote 3 and Section I-D-6) to "and the absence of harmful sequences established." I have also decided that the 99 percent criterion should be retained in the present revision of the guidelines; but this point will be reconsidered by the RAC as a possible item for future revision.

Section III-B. Experiments with Other Prokaryotic Host-Vectors

Several correspondents addressed the use of hosts other than *E. coli* K-12. They pointed out that many experiments with such hosts are "inadvertently prohibited," and suggested wording to allow experiments in hosts other than *E. coli* K-12 which do not meet the criteria for HV1.

In the proposed revised Guidelines, experiments with prokaryotic hosts other than *E. coli* K-12 fall into the following classes: (i) Self-cloning, exempted under the exemption I-E-3; (ii) return of DNA segments to non-HV1 host of origin, Section III-B-2; and (iii) use of HV1 systems, Section III-B-1. I agree that there are many safe experiments which fall into none of the above three classes but which should be allowed under specified containment levels. The proposed revised Guidelines, at the beginning of Section III, stated, "... (or the assignment of levels to experiments not explicitly considered here) may be expressly approved by the Director, NID, on the recommendation of the Recombinant DNA Advisory Committee (RAC)." This language has been retained in a slightly modified form in the final Guidelines. In addition, similar language is now repeated in a new Section III-B-3 and at the end of Section III-C-5.

A specific example of this type of problem was provided by a commentator who cited experiments he would like to perform involving recombinant DNA from *Bacillus popilliae*, a patho-

gen for the Japanese beetle, and *Bacillus thuringiensis*, a pathogen of pest caterpillar larvae. He asked for clarification of what containment levels would apply under the proposed revised Guidelines.

The experiment could be considered under several different provisions. If data are submitted on natural exchange of DNA between *B. popilliae* and *B. thuringiensis*, these organisms could be listed in a future version of Appendix A as falling under exemption I-E-4. Or under the new paragraph III-B-3 which has been added to the Guidelines, containment levels could be set for these experiments.

Section III-C. Experiments with Eukaryotic Host-Vectors

A general issue raised by one respondent concerns the stipulation that some experiments will be assigned containment levels on a case-by-case basis. The commentator is concerned that this approach ignores the need for minimum standards which can serve as a guide for research workers.

I believe that the case-by-case analysis prescribed for many experiments involving the employment of viral DNA as a vector reflects the caution exercised over the use of such DNA. Each such experiment is thus prohibited until the RAC has had a chance to weigh the scientific evidence and propose whether the experiment should proceed and, if so, to assign appropriate physical and biological containment levels.

I have accepted several other recommendations for changes in this section. Two commentators offered new language for the section dealing with requirements for the employment of defective adenoviruses as cloning vectors. They noted that new mutants of Ad5 or 2 in which the entire transforming region has been deleted have recently been isolated. These mutants can only be propagated in adenovirus-transformed cells. The commentators suggested that the language in Section III-C-1-c-(1)-(a) be generalized to state: "Human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least two essential genes, with appropriate helper, can be used under P3 conditions to propagate DNA sequences from * * *." I believe this is justified, and the Section has been modified by changing the word "capsid" to "essential."

A correspondent stated that Section III-C erroneously equates nonproductive infections with nonpermissive cells. He pointed out that in certain situations nonproductive infections may result from infection of permissive cells. I agree. Accordingly, the phrase "to transform nonpermissive cells in culture" has been eliminated at a number of places in Section III-C,

and more appropriate language has been substituted.

The same correspondent pointed out that in Section III-C the word "intact" is not appropriate because as soon as a foreign sequence is introduced, the viral DNA is no longer intact. I agree. The wording in the relevant sections has been changed from "intact" to "whole."

Section III-C-2, Invertebrate Host-Vector Systems in Which Insect Viruses Are Used to Propagate Other DNA Segments. Section III-C-3, Plant Viral Host-Vector Systems. Section III-C-4, Plant Host-Vector Systems Other than Viruses

I have considered the comments for these three sections in a single group.

A witness questions "the necessity for EPA registration of an entomopathogenic organism in lieu of simply meeting the criteria of EPA for a temporary exemption from a requirement of tolerance in the environment."

In the proposed revised Guidelines published in the FEDERAL REGISTER on September 27, 1977, "baculoviruses which have been registered by the Environmental Protection Agency" are specifically discussed in the section dealing with invertebrate host-vector systems in which insect viruses are used to propagate other DNA segments. The writer is apparently addressing this section and requesting that the EPA registration not be required but merely "the criteria of EPA for a temporary exemption from a requirement of tolerance in the environment." The analogous section (III-C-2) in the proposed revised Guidelines published in the FEDERAL REGISTER on July 28, 1978, does not in fact refer to EPA registration as a specific criterion. It indicates that experiments in which insect viruses are used to propagate other DNA segments will be evaluated on a case-by-case basis by the Recombinant Advisory Committee. Information required for a judgment includes host range restrictions, and infectivity, persistence, and integration of the viral DNA. Data submitted by the requesting investigator on whether EPA has registered a given insect virus or whether it meets the EPA criteria for a temporary exemption from a requirement of tolerance in the environment will be considered by the RAC.

The same witness also questioned the validity of the statement in Section III-C-3 that "the plants should be grown under P1 conditions—that is, in either a limited access greenhouse or plant growth cabinet which is insect-proof" and suggested substitution of the term "insect-restrictive" rather than "insect-proof," since the latter term implies higher containment. I

concur with the recommendation and have made the change.

On the other hand, I do not agree with the opinion of the correspondent who questioned the relevance of P1 or P2 containment conditions to experiments in which recombinant DNA is cloned in higher plants. The correspondent believes that higher plants containing nonviral recombinant DNA should not require any containment. The proposed revised Guidelines (pages 33082 and 33084 in the *FEDERAL REGISTER* July 28, 1978) specifically define special P1 and P2 conditions for work with plants. I do not believe that recombinant DNA work with higher plants should now be done with no containment at all.

Finally, I have considered the request of two correspondents discussing employment of the tumor insertion plasmid (Ti) of *Agrobacterium tumefaciens* as a cloning vector. They suggest adding the following sentence to Section III-C-4: "Inoculation of hosts with HV1 approved *Agrobacterium* containing the DNA recombinants requires P2 physical containment." I do not believe inclusion of the sentence is warranted at this time. Data on the system can be submitted to the RAC for approval as an HV1 system. If approval is granted, the RAC at that time can recommend the appropriate containment level.

Section III-D. Complementary DNAs

Two correspondents were concerned over the possibility of eukaryotic DNA being expressed in prokaryotic cells. They noted that genes cloned via a shotgun experiment will probably not be expressed because they retain their intervening sequences and the resulting RNA is not likely to be processed. On the other hand, complementary DNA prepared from messenger RNA could serve in turn as a template for synthesis of the same RNA within the prokaryotic cell. They suggest that a "distinction should be made between eukaryote DNA and cDNA formed from mRNA."

In responding, I must note that containment levels for eukaryotic DNA were developed on the assumption that such DNA, no matter what the source, could be expressed. The proposed Guidelines set the same containment levels for eukaryotic DNA and cDNA formed from functional eukaryotic mRNA. For cloning of viral DNA into *E. coli* K-12, however, there are differences in the containment levels depending on whether one is using the viral DNA itself or cDNA from viral mRNA (see Table III). The probable future uses of cDNA copies of functional mRNAs are discussed in the Introduction and Overview of the Director's Decision (*FEDERAL REGISTER*, July 28, 1978, pp. 33044 and 33047).

Section III-E. Synthetic DNA

A correspondent argued that the discussion of appropriate containment levels for synthetic DNA that codes for harmless polypeptide products "makes no sense." He asks, "Why is any containment required for a harmless product?" and recommends the following alternative language for this section: "If the synthetic DNA sequence codes for a harmless product or if the synthetic DNA is not expressed *in vivo*, the organisms containing the recombinant DNA are exempt (4) from the Guidelines."

In reply, the term "harmless product" refers to the normal toxicity or pathogenicity of the protein and not necessarily to the remote possibility of its otherwise disrupting the physiological balance of the organism in which it might inadvertently be introduced. I believe that the language of the NIH-proposed revision should remain as published, since the three paragraphs describing containment for synthetic DNA clearly describe three distinct concepts. The provisions of Section III-E are consistent with those of III-A-3 dealing with containment levels for purified or characterized DNA.

IV. ROLES AND RESPONSIBILITIES

RESPONSIBILITIES OF THE INSTITUTION (GENERAL)

Institution

The general responsibilities of the institution are to ensure appropriate review and implementation procedures for all of the institution's recombinant DNA activity that is covered by the Guidelines. Below are a number of general institutional responsibilities that were addressed in correspondence and by witnesses at the DHEW public hearing.

Exercising Institutional Authority. Both groups of commentators stated that the Guidelines should permit the institution to set new requirements beyond those of NIH. In the Guidelines, the institution has this authority, and a provision has been added specifically stating that the institution may establish requirements and procedures for the general implementation of the Guidelines, including additional precautionary steps if deemed appropriate. It should be noted, however, that these Guidelines and the standards they embody are conservative and in no way constitute a minimum set of requirements.

Establishing an Institutional Biosafety Committee. Requirements for membership on the Institutional Biosafety Committee (IBC) drew substantial attention in the letters and at the public hearing. Much of the comment was directed to mandating various representation. Some commentators sug-

gested that a local public health official and a nondoctoral person from a laboratory technical staff serve on the committee. Others recommended mandating community leaders who are "in touch with grass roots attitudes," including "environmentalists." Others suggested that the membership reflect the demographic distribution of the community in which the institution is located. Requirements for membership distribution by age, sex, income level, professional background, and other variables were mentioned. It was suggested that at least two members be custodial or janitorial workers. Others recommended that there be at a minimum one physician trained in infectious diseases, one epidemiologist, and one environmental scientist.

Other commentators and witnesses suggested various ratios of scientists and nonscientists serving on the committee. Some urged that one third of the membership represent "the interest of the community" and another third "scientific disciplines related to risk assessment." It was also suggested that nominating procedures be specified for selecting community representatives.

On the other hand, some commentators believed that the proposed revision was presumptuous in mandating lay representation on this committee, especially when the university may already have several lay committees for oversight.

Others suggested that the minimum membership for an IBC be raised from five to seven. The minimum of five members is recommended to take into account small universities with few projects. In these and many other cases, five is sufficient, and it remains as the minimum. Membership recommendations in the revised Guidelines attempt to balance professional expertise with members who represent the interest of the surrounding community. As pointed out by one correspondent, however, the IBC, in contrast to human-subject committees where broad concepts of social and ethical values are considered, is in large part an expert committee whose essential function is to evaluate research protocols in respect to containment levels, using the explicit instructions of the Guidelines. Rigid quotas are not necessary. Indeed, many small academic institutions would have considerable difficulty meeting specified demographic requirements. The IBC criteria are flexible to permit the institution to select a committee capable of fulfilling its responsibilities.

The DHEW Committee carefully reviewed all the comments and considered at great length membership requirements for the IBCs. On balance, it was decided that the interest of the surrounding community could be

served, as one commentator suggested, by "at least two members." In addition, at least 20 percent of the committee shall not be affiliated with the institution and shall represent the interest of the surrounding community with respect to protection of the public health and the environment. Moreover, nomination procedures need not be specified, but should be left to the discretion of the institution for the selection of these members.

With respect to conflict of interest, some commentators recommended that IBC members be prohibited from any direct involvement in recombinant DNA or closely related research unless the member is a laboratory worker. The conflict-of-interest provisions in the Guidelines respond to these concerns while reflecting the paramount need for relevant scientific competence on the IBCs.

A commentator stated that "peer review does not adequately protect the public," citing instances of noncompliance with the Guidelines at two NIH grantee institutions. It should be noted that the two cases in point involved administrative violations and presented no risk to the public health or the environment.

Some of the commentators from the private sector expressed concern that the financial conflict-of-interest statement required in the Guidelines might be interpreted as denying IBC membership to any member of a company. Others felt that a requirement for public members would present problems of protecting confidential information. However, at a meeting of the DHEW Committee and representatives from the Pharmaceutical Manufacturers Association, it was agreed that public members could and do serve on the committees. Some are asked to sign agreements to honor confidentiality of proprietary and patent information.

Health Surveillance. This area was one of deep concern to some witnesses and correspondents. Witnesses at the September 15 hearing made several suggestions concerning medical surveillance, and correspondents suggested that the term "medical surveillance" be changed to "health-risk surveillance" or "health surveillance." That suggestion has been adopted in the Guidelines.

Several commentators and witnesses urged that health surveillance programs be required in the Guidelines. Concern was expressed that without such a requirement different standards and different programs would result. In addition, there were many suggestions from commentators, including the Occupational Safety and Health Administration (OSHA), about what should constitute a health surveillance program—for example, com-

plete medical histories, periodic medical checkups, and serial serum samples. It was recommended that laboratories be required to keep official OSHA health and safety log forms, and that records be kept of all agents use, all modified organisms created, and all laboratory-acquired illnesses.

Several commentators also called for a clearinghouse, to be established at the Federal level, at which copies of all health surveillance plans and records would be filed. It was urged that NIH maintain such data, including records of workers in laboratories using recombinant DNA techniques, with particular regard to instances of possible work-related illness. There were also several suggestions for a national epidemiologic monitoring and surveillance program to be supported by DHEW. Such programs might, as one commentator suggested, promote national standards for health surveillance specific for each class of organisms and group of experiments. And finally, there were suggestions for ongoing epidemiologic and biostatistical analysis of data as they are accumulated to permit early detection of trends.

I reviewed these issues in the Decision document accompanying the proposed revised Guidelines as published in the *FEDERAL REGISTER* July 28, 1978. As I noted in that document, the issue of medical monitoring is one of considerable interest to NIH and is not unique to recombinant DNA research. The "state-of-the-art," however, is primitive in terms of effective monitoring of workers' health generally, and particularly in recombinant DNA research, where there is no known hazard.

One commentator noted that the Cambridge, Massachusetts, city ordinance for recombinant DNA research requires the institution, as part of its health surveillance responsibility, to monitor survival and escape of recombinant DNA organisms in each laboratory worker engaged in this type of research, as by the testing of intestinal flora. Intestinal flora sampling is being undertaken at MIT. NIH will follow the MIT program closely. This is not the time, however, to propose extension of that experiment to general practice.

We recognize the need to aid the institutions as much as possible in this important area. The laboratory Safety Monograph provides extensive detail and guidance. It suggests monitoring illnesses, collecting serum samples, and keeping a register of agents handled. Moreover, the Guidelines now require the institution (rather than the principal investigator) to determine, in connection with each project, the necessity for health surveillance of relevant personnel and to conduct a health surveillance program appropri-

ate to the project. And the Memorandum of Understanding and Agreement will include reference to health-surveillance programs associated with the project.

In response to the calls for a national clearinghouse, it should be pointed out that the NIH Office of Recombinant DNA Activities (ORDA) has been designated in the Guidelines to receive, review, and maintain certain medical and accident information. Through ORDA, NIH will have a collection of essential data which should provide the ability to discern if certain experiments result in unique health problems. It is emphasized, however, that for any health surveillance to be truly effective, it must be conducted at the local level.

RESPONSIBILITIES OF THE INSTITUTION (SPECIAL)

The special responsibilities of the institution include establishing general policies, appointing the Institutional Biosafety Committee (IBC), appointing a Biological Safety Officer (BSO) where required, and reviewing and implementing procedures applicable to the submission of the Memorandum of Understanding and Agreement (MUA). A number of commentators and witnesses addressed these requirements.

One commentator recommended that the signature of an institutional official not be required on the MUA (in Appendix C of the July 28 revision), but that the IBC chairperson should represent the institution. The signature of an institutional official on the MUA is requisite, for that individual is authorized to act for the institution and assume on its behalf the obligations imposed by the Guidelines. If the institution so wishes, however, it may designate the IBC chairperson as the responsible official for MUAs that do not require prior NIH approval. This is newly noted in the Guidelines and the Administrative Practices Supplement (APS), which now incorporates Appendix C.

The correspondent also recommended that MUAs for fellowships, as found in Appendix C, be deleted as an unnecessary duplication of effort. This recommendation is sound, for it is duplicative to require an MUA when the projects are registered. Thus, MUAs will not be required with fellowship applications.

Another correspondent called for clarification of the difference, if any, between the IBC's procedures for review of NIH-funded and non-NIH-funded projects. The information required for NIH- and non-NIH-funded projects in an institution receiving NIH support for recombinant DNA research is similar. Further information on the requirements has been included in the APS. For purposes of IBC

review and monitoring responsibilities, there should be no distinction between NIH- and non-NIH-funded projects.

Another commentator urged that the Guidelines give greater detail on the types of protocol changes for which a new or revised MUA must be sent to NIH. Information previously contained in Appendix C has now been added to the Guidelines to clarify this point, and further information is contained in the APS.

Another commentator suggested that the institution be required to notify a local Health Systems Agency upon filing an application for Federal support of recombinant DNA research. This is not applicable to HSA responsibilities under section 1513(e) of the PHS Act and therefore is not mandated.

Another correspondent requested that Appendix C be mandated. The test of Appendix C, now in a supplement to the Guidelines (the APS), has been extensively rewritten, and many of its features have been incorporated in the Guidelines for purposes of clarification. I agree that the provisions now in the Guidelines should be mandatory.

Institutional Compliance. A commentator challenged the right of NIH to require an institution to hold that all principal investigators, irrespective of source of funding, must follow the Guidelines. This requirement, however, is vital to the maintenance of uniform standards and is therefore retained. On the other hand, research supported by another Federal Agency need not be registered with NIH when that agency maintains a registry and provides NIH with essential information.

Another commentator suggested delegating responsibilities for all enforcement of the Guidelines to the institution (IBC), with ORDA receiving periodic reports from the committees on the research they are regulating. There are several reasons such a course would be unwise at this time. Exercise of any discretion is a new responsibility for the IBC's. Uniformity and expertise must be demonstrated by verification through NIH review. A great deal of standard-setting, necessarily central at present, is yet to be done through case-by-case analysis.

One commentator requested that the NIH notify both the IBC chairperson and the institution when it was reviewed each action of the IBC according to the information submitted on the MUA. This, I believe, would strengthen coordination of compliance efforts. The final Guidelines accordingly require the double notification.

It was also suggested that NIH provides a statement that it has certified the institution and finds it to be in compliance. This request is related to

requirements in State regulations that go beyond the Guidelines. However, NIH plans to provide official documentation to institutions in States requiring such information. The subject will be further treated in the APS.

Another commentator urged NIH to devise a system to protect those who report possible violations. This issue was reviewed in my Decision accompanying the proposed revised Guidelines (FEDERAL REGISTER, July 28, 1978, p. 33065), where I noted that grievance procedures for workers under the Guidelines were not considered necessary because OSHA rules and regulations already provide such a mechanism. However, witnesses at the September 15 hearing and comments from OSHA state that the Occupational Safety and Health Act does not cover employees of State and local governments unless the State operates under an OSHA-approved State plan covering health and safety practices and grievance procedures. Only 23 States currently have such plans. But other States presumably have similar statutory protection, and it would be presumptuous of NIH to attempt to detail specific grievance procedures in all jurisdictions. The Guidelines require the reporting of violations and allow the reports to be made to NIH by anyone. The institutions, I believe, will accept such reports in a positive light and as an important aid in maintaining compliance with the NIH standards.

Institutional Biosafety Committee (IBC)

The principal functions of the IBC are to review and oversee all recombinant DNA projects with respect to compliance with these Guidelines and to advise the institution and ORDA whether the proposals and the research so comply. A number of issues concerning IBCs were addressed by the commentators and witnesses at the September 15 hearing, including delegation of authority to the IBCs, public representation on the committee, and public access to its proceedings.

Delegation of Authority. Several correspondents and a number of witnesses at the September 15 public hearing took exception to the delegation of authority to the institutions and their IBCs to act on certain experiments without prior NIH approval. One witness noted that there has been a 4 to 15 percent error rate by the IBCs. He also noted that NIH review did not entail inordinate delays, citing the usual review at ORDA as taking only 4 to 5 days. He urged that NIH retain the present two-level system of review requiring prior NIH approval for all projects. The data here do not take into account additional referrals of MUSs between

ORDA and various NIH Institutes supporting such research. These have introduced delays of many days or weeks in processing. Other commentators recommended quite the opposite—that greater latitude be given the IBCs to assign containment levels for experiments.

The reason for the delegation of authority is extensively discussed in my Decision and the Environmental Impact Assessment accompanying the July 28 publication of the proposed revised Guidelines. As stated in the Decision document, the increased responsibility of the institution is in response to comments calling for a simpler administrative process and more local responsibility. It is also a recognition of the practical requirements for enforcement of standards for use of such highly varied and complex technology in many institutions spread over a vast area. As stated by the House Committee on Interstate and Foreign Commerce in its report of March 28, 1978, on the Recombinant DNA Act: " * * * the appropriate portions of the administrative requirements of section IV of the NIH Guidelines are a reasonable model upon which the Secretary could base administrative regulations. In particular the current practice in the NIH Guidelines of delegating to local biohazard committees most of the responsibility for the inspection of the facilities and the approval of the specific safety requirements appropriate to each project or activity is an effective and relatively inexpensive administrative mechanism." Thus, the delegation of increased responsibility at the local level is not primarily to facilitate an increased volume of research, as suggested by a commentator, but rather to place this function at the most appropriate location for initial enforcement of the Guidelines. It should be noted, however, that MUAs, before going to ORDA, go to the NIH Institute funding the research, and there have been delays of days or weeks at this level, adding substantially to the time required for processing. We will consider means to simplify procedures so the ORDA can respond in a timely fashion to the institutions.

The DHEW Committee carefully considered the issue of prior NIH approval. On the basis of that review, the Guidelines now specify the circumstances in which prior approval is required, with greater detail provided in the APS. In addition to the five categories of experiments requiring prior approval in the NIH proposal, prior approval is now required, on the recommendation of the DHEW Committee, for the first project to be conducted by an institution and the first project in a facility at P3 containment.

It should be emphasized that while the delegation to the IBCs permits initiation of all other research at the local level, the NIH review and approval of all research under the Guidelines will continue as before. All protocols not found to be in conformance must be modified. Given the slowly increasing sophistication of investigators and IBCs alike, plus the provision in the Guidelines of explicit standards for performance of their duties, I am confident that this delegation will in no sense present risks to the health or the environment.

It should also be noted that some commentators still regard proposed administrative procedures as "excessive and disproportionate when measured against the perceived risks." They are especially concerned that the work of the IBCs is taxing the human and financial resources of the institution. That a burden is placed on the local institutions cannot be denied, but the responsibility is better delegated than retained at the Federal level. As we learn more, there will presumably be less and less need for formality and centralized review in the governance of this research. In anticipation of probable decentralization with time, creation of the local capability must begin without delay.

Another commentator urged that the Guidelines be extended to all hazardous biological research. As stated in my Decision of July 28, I do not believe we can or should extend the Guidelines to other research at this time. However, the entire area of laboratory safety is of prime concern to NIH and the subject of constant review and attention. NIH activities in this area are described in the Environmental Impact Assessment published with the Guidelines as proposed in July. It should be noted that some IBCs, as one correspondent pointed out, assume the added duty of monitoring work with known pathogens that is not related to recombinant DNA technology.

In view of the delegation, some commentators urged that there be more financial support for the operations of the IBC. It was recommended that NIH require some percentage of the overhead charged on recombinant DNA research proposals to be earmarked for operation of the IBCs.

Concern has been expressed in the past about the cost of the IBC operations. As stated before, NIH already pays for the operations of such committees through reimbursement of so-called indirect costs of research. I do not believe there is need at this time to separate them from other indirect costs of the institutions.

Reduction of Containment Levels. A number of commentators and witnesses questioned the authority of the

IBC to lower containment requirements for certain experiments. On the other hand, many believe the IBCs should be authorized both to reduce and to raise containment levels. It should be understood clearly that the IBCs' authority to lower containment levels is quite limited and governed by strict standards and procedures set forth in the Guidelines. NIH is notified of all such discretionary actions. It will review them and require that any failures to come up to the standards of the Guidelines will be corrected.

Specifically, the IBC can reduce containment levels only for experiments using purified DNA and for characterized clones. Standards and procedures for the former action are stated in Section III-A-3-a of the Guidelines and in Footnote 41; those for the latter action, in Section III-A-3-b and in Footnote 3. Standards for both actions appear also in the IBC section of part IV of the Guidelines and in greater detail in the Administrative Practices Supplement. Further, it should be noted that NIH approval is required for any lowering of containment levels below Pl + Ekl, or by more than one step, or for experiments involving primate DNA.

Specific authority is granted to the institution (Section IV-D-1) to establish requirements deemed necessary for the implementation of these Guidelines. The IBC, then, can raise containment levels. The national standards, however, are very conservative, and in my view, to raise them generally or for characterized clones and purified DNA is unwarranted.

Appeals. Several commentators advocated, in light of the authority delegated to the IBCs, procedures for "appealing a decision of the local IBC against a project or against a certification of facility." The Guidelines do not prescribe an appellate mechanism. A full partnership of investigators and their institutions is intended in maintaining compliance with the Guidelines. The investigators and the IBCs must not be cast in adversary roles, and NIH will make every effort to promote their cooperation. We will be available on request to provide technical advice and consultation with principal investigators and institutional committees alike.

Emergency Plans. The IBC has responsibility to review and approve emergency plans. A number of commentators suggested greater detail in the Guidelines on the emergency procedures to be employed, including specification for cleanup procedures to be followed should there be a spill or accidental release of organisms into the environment. Other commentators suggested that the Guidelines set national standards for the handling of

emergency spills. Several urged that the biosafety officer at each institution be charged with responsibility for drafting such plans.

The Laboratory Safety Monograph presents guidance on pages 194-196 on procedures to be followed in emergencies. Some of that information is now included in the Guidelines to emphasize its importance. The monograph will be revised further, in response to comments, to provide greater detail and to include emergency numbers at NIH and the Center for Disease Control that can be called on a 24-hour basis. The two agencies will provide consultation and direct assistance if needed. In addition, the Guidelines specify that the institution shall cooperate with the State and local public health departments and report to them any illness or laboratory accident that appears to be a hazard to the public health. And the IBC chairperson is responsible for notifying the institution and NIH, within 30 days, of problems with the Guidelines, violations, or significant research-related accidents or illnesses, unless the chairperson finds that the PI has done so.

Public Access. Several witnesses at the September 15 hearing and many commentators urged greater public access to proceedings of the IBC. The proposed revised Guidelines required that minutes of the IBC meetings be made available to the public upon request. However, there were several suggestions for further requirements. Witnesses urged that the IBC meetings be publicized and open to the public, except for those specifically dealing with proprietary or other confidential information. Suggestions were made to enhance public participation through evening meetings of the committee and the use of lay summaries of research proposals. Procedures were recommended for announcing IBC meetings. Others recommended that all MUAs and reports of inspections be made publicly available.

The DHEW Committee spent a great deal of time reviewing comments about this portion of the Guidelines. In my Decision accompanying the proposed revision of July 28, I noted that possible discussion of proprietary and patentable information often precludes open IBC meetings. I did urge, however, that local committees have open meetings when possible and that they be publicly announced.

In response to the issues raised, and in view of the increased responsibility given to the local institutions, the final Guidelines require, in addition to public representation on the committee, public access to proceedings of the IBC. Institutes are encouraged to open IBC meetings to the public whenever possible, consistent with the protec-

tion or privacy and proprietary interests.

In addition, the IBC is to forward to NIH any public comments made on its actions and the committee's response to them. And all IBC documents that NIH must make available to the public, such as the funded research proposals, are also to be made available, upon request, at the local level. These include reports of serious accidents and of problems with and violations of the Guidelines; also all NIH reports to institutions when MUAs (including modifications of ongoing projects) are not in compliance. Likewise, minutes of the IBC meetings and inspection reports will be made available. The intention of the Guidelines in all these changes is to enhance public accountability at the local level.

Biological Safety Officer

There were a number of comments concerning the roles and responsibilities of the Biological Safety Officer (BSO). Several witnesses at the September 15 hearing recommended that whenever recombinant DNA research is being conducted at an institution, such an officer be appointed and required to serve on the IBC. It was also recommended that the BSO have a full-time position. The Committee considered the role of the BSO at some length.

The Guidelines do specify that all institutions conducting work at the P3 and P4 levels must have a BSO. The officer is required at those levels because the sophisticated equipment and facilities require special abilities. The Laboratory Safety Monograph (p. 191-193) outlines the qualifications and role. But the Guidelines do not mandate such an officer for P1 and P2 work because the potential risk at those levels is minimal and the expertise readily available for laboratory safety. The Committee concurred with this view.

Other commentators recommended that the Guidelines assign to the BSO responsibility for monitoring, keeping records, and health surveillance. The DHEW Committee reviewed the qualifications of BSOs, noting the absence of certification procedures for such a new and ill-defined discipline. Accordingly, it was agreed that certification requirements should not now be stipulated for BSOs and that flexibility should be encouraged to permit a BSO to have responsibilities for such activities as health surveillance. As noted in the LSM, one can call on the environmental health and safety program at the institution to assist in a variety of the duties suggested for the safety officer.

The BSO is responsible for developing emergency plans, and the NIH will provide assistance for program devel-

opment. But in my view, it is far more sensible at present to begin emergency plans at a local level than to attempt to develop them on a grander scale until any hazards are better understood. Unless the principal investigator has already done so, the BSO is also responsible for providing reports to the IBC and the institution on problems with and violations of the Guidelines and on all significant research-related accidents and illnesses.

Principal Investigator

As stated in the introduction to part IV, safety involving recombinant DNA molecules depends in the first instance on the individuals conducting the research. The Guidelines are designed to help the Principal Investigator determine the safeguards that should be implemented, and it is his or her responsibility to ensure that the purpose of the Guidelines is fulfilled. A number of the comments were devoted to the PI's role in laboratory safety and training.

Training. Many of the correspondents and several of the witnesses at the September 15 hearing recommended training programs for all laboratory personnel, including custodial personnel, the members of the Institutional Biosafety Committee, the Biological Safety Officer, and all relevant institutional officials. One commentator recommended that laboratory workers in P2 or higher facilities take and pass training courses or demonstrate equivalent competency before working directly with organisms containing recombinant DNA. Further, a centralized and uniform certification process for workers at the P3 or P4 level was advocated. It was urged that the Guidelines not be revised until there are uniform procedures for training certification of all biosafety officers and all recombinant DNA laboratories at the P2 or higher levels. Some suggested the Biological Safety Officer should be responsible for the certification process.

A number of commentators advised further that the Guidelines specify components of training for a program available to all potentially exposed workers. It was also recommended that the PI make available copies of approved protocols that describe potential biohazards and precautions, not only to the research personnel but also to the custodial staff. It was further suggested that NIH and OSHA should jointly sponsor technical and educational programs for IBC members and Biological Safety Officers.

I appreciate the concern regarding the quality and uniformity of training. As I stated in my Decision document (July 1978), NIH is responding to this by placing a high priority on the development of training standards and

courses. For example, we are supporting, as noted previously, a working panel of the American Society for Microbiology that is considering standards for training in microbiological techniques for recombinant DNA research. When a report is submitted to NIH, it will be shared with institutions, IBCs, PIs, and BSOs. National certification of proficiency in any research technology is fraught with problems, especially in areas in which knowledge is increasing rapidly.

NIH is already sponsoring and developing courses on these standards of training. For example the University of Minnesota School of Public Health has developed and conducted a series of short courses on "Biohazard Containment and Control for Recombinant DNA Molecules" under the sponsorship of the National Cancer Institute's Office of Research Safety. The objective is to instruct laboratory workers on the principles of safety in the research laboratory and, particularly, on their application to the safe handling of recombinant DNA molecules. To date, six courses have been presented. A total of 221 participants from 97 institutions have attended. They have come from 7 government laboratories, 34 private or industrial laboratories, and 56 universities.

The Office of Research Safety, NCI, is also developing a training course for biosafety officers on practices and procedures for the control of biohazards in the research laboratory. The purpose is to equip biosafety officers with the basic knowledge and skills to carry out effectively the responsibilities specified in the NIH Guidelines. Detailed instruction on methods for evaluating, certifying, and monitoring physical-containment safeguards will be offered. Guidance will also be provided on how to organize, plan, develop, and conduct a comprehensive biosafety program.

NIH plans to further the biosafety training efforts of institutions by providing on-site consultation. The program will be designed to assist institutions and their IBCs, biosafety officers, and laboratory workers in effectively carrying out the requirements of the Guidelines. Biosafety professionals will be available to visit institutions and assist them in evaluating and improving their safety programs. These professionals will also be available to help solve specific problems in physical containment. A principal element of the program will be to promote good laboratory practice and to reinforce its importance.

Training of laboratory workers is a continuous process required under the Guidelines. One commentator expressed uncertainty as to who has the responsibility for seeing that personnel are trained in safety practices and

techniques. The DHEW Committee reviewed this matter, and on the basis of the review, the responsibilities have been clarified. The institution is responsible for ensuring appropriate training for IBC chairpersons and members, laboratory staff, and the BSO. The IBC chairperson will brief the IBC members and provide whatever information on training is required for them to fulfill their responsibilities. To the PI is delegated responsibility for training all the laboratory workers involved in the project.

Safety Practices. The PI is responsible for correcting work errors and conditions that may result in the release of recombinant DNA materials. Several commentators suggested that any accidental release of recombinant organisms, regardless of suspected pathogenicity, be reported to the proper health authorities. The Guidelines now require the institution to report to State and local health departments any significant research-related illness or accident that appears to be a hazard to the public health.

Another commentator suggested that the PI be required to halt ongoing research if any problems result in a failure to meet assigned containment requirements. It was suggested that the research be halted for 24 hours while a report is made to the IBC. The IBC would then certify in writing that the necessary repairs have been made. The Guidelines require reporting and correction of such problems by the investigator, but they do not specify a time limit except that reports must be made to NIH within 30 days on any significant problems with the Guidelines, on violations, and on all significant research-related accidents and illnesses. Nor do they require the IBC to document the repairs. While these mandates are not necessary, the institution should consider setting such policies as deemed necessary. The Laboratory Safety Monograph and the Guidelines contain increased information on health surveillance to assist the PI in his responsibilities in this area.

Exemptions and Exceptions. Another commentator suggests that the PI receive IBC approval before petitioning the NIH for exemptions to the Guidelines or exceptions to the prohibitions. In light of the enhanced responsibilities of the local IBCs, it is appropriate for them to review proposals for exceptions to the prohibitions. Accordingly, the Guidelines now state that proposals to NIH must be submitted with the concurrence of the IBC.

Proposals for exemptions from the Guidelines deal with alterations in standards applied to all engaged in this research. Scientists may send those proposals directly to NIH for the considerations of the RAC with

notice to the IBC. Note of exemptions granted will be sent to all IBCs. Experiments that are exceptions to the prohibitions require approval at the national level, after which they must be reviewed and approved by the IBC. An MUA must then be approved by NIH before the experiment may be initiated.

MUAs. Several commentators suggested that the Guidelines be clarified with respect to the types of experiments that may not be started prior to NIH approval. As noted previously, the Administrative Practices Supplement is responsive to the suggestion, and more guidance is given in the section of the Guidelines on "Institutions" (IV-D-1) to clarify the preparation and submission of MUAs for new and modified experiments.

Publication. The Guidelines recommend that published research articles specify the containment procedures used. A commentator advocates that this be required. The issue has been raised before, and it remains our view that NIH neither can nor should control what must be included in scientific publications.

RESPONSIBILITIES OF NIH (GENERAL)

Due Process Considerations

A number of commentators spoke on the issue of public participation, including how best to inform the public and ensure public access to NIH proceedings. A number of commentators and witnesses at the September 15 hearing focused on the provisions calling for "appropriate notice and opportunity for public comment." Several suggested that those provisions be described in greater detail in the Guidelines. Other commentators urged that labor and environmental representatives, consumer advocacy groups, public health officials, and government agencies with potential regulatory responsibility have full access to decision-making.

Some commentators called for clarification of procedures for certifying host-vector systems. Others asked that the standards and procedures for future Guideline revisions be explicitly stated. Another wanted procedures that clearly set forth public notice and comment in advance of RAC decisions. And another believed the proposed Guidelines "exacerbate the problems of self-regulation" and urged that "HEW supervise the administration and enforcement of the Guidelines."

One commentator suggested a procedural mechanism for minor or partial revisions. He advised that RAC recommendations be published in the FEDERAL REGISTER for comment, and that the comments be taken into account by the RAC before it forwards final recommendations to the Director. Thus, NIH in these cases would act in

the light of advice reflecting public views.

Another commentator suggested that each time NIH receives an application for an exception to a prohibited experiment, notice be published in the FEDERAL REGISTER, and that after a public comment period, final notice of agency action should also be published there.

NIH Procedures. The NIH Guidelines of 1976 provided little or no discretion in their administration or revision. As a result, many recommendations by the RAC could not be accepted because of NIH's lack of authority under those Guidelines to approve them. The revision proposed by the RAC in September 1977 attempted to correct this inflexibility by providing for discretion under specified conditions, with procedures set forth to ensure opportunity for public notice and comment. However, the standards and procedures for exercise of discretionary authority in the proposed revision, as many of the commentators pointed out, needed greater definition and clarity.

The commentators' procedural recommendations provided a focus for the DHEW Committee in its intensive review of these issues in the proposed revisions. Other comments from the scientific community, from many witnesses at the public hearing, and from a DHEW meeting with environmental interest groups augmented the efforts to define avenues for appropriate utilization of NIH authorities. On the basis of the comments made in correspondence and at the September 15 hearing, part IV has been substantially revised to provide for public access and participation in NIH activities under the Guidelines. It clearly sets forth the procedures that will govern the exercise of NIH authority.

First, there is a group of major actions for which the NIH Recombinant DNA Advisory Committee (RAC) will advise the Director after an opportunity for public and Federal agency comment. These actions include lowering or assignment of containment levels where the Director judges the action to be major; certification of new host-vector systems; exceptions to the prohibitions; modification of a list of recombinant DNA sources (microorganisms) to be exempt from the Guidelines and other changes in the Guidelines.

For these major actions the following procedures apply. The Director must seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the agenda of the RAC meeting citing the major actions will be published in the FEDERAL REGISTER at least 30 days before the meeting, and the Director will simultaneously publish the pro-

posed actions in the *FEDERAL REGISTER* for comment. In addition, the Director's proposed decision, at his discretion, may be published in the *FEDERAL REGISTER* for 30 days of comment before final action is taken. The Director's final decision, along with response to the comments, will be published in the *FEDERAL REGISTER* and the *Recombinant DNA Technical Bulletin*. The RAC and IBC chairpersons will be notified of this decision.

There is a group of lesser actions for which the RAC will advise the Director after a meeting announced as described above. These actions include all interpretations of determinations referred by ORDA, changes and assignment of containment levels, approval of large-scale experiments for rigorously characterized recombinant DNA where the absence of harmful genes has been established, and designation of certain class 2 agents as class 1 for purposes of the Guidelines. The Director's decision will be transmitted to the RAC and IBC chairpersons and published in the *Recombinant DNA Technical Bulletin*.

And finally, there is a group of administrative and scientific functions in the Office of the Director that may be delegated to the Office of Recombinant DNA Activities (ORDA), involving implementation of the Guidelines and their interpretation. Again, decisions by the Director in these matters will be published in the *Recombinant DNA Technical Bulletin*, and notice will be given to the RAC and IBC.

There was considerable Committee discussion on the standards to guide administrative discretion. It was agreed that the Guidelines should set forth a general standard. Accordingly, they now charge the Director to "with each proposed action, through appropriate analysis and consultation, to determine that it complies with the Guidelines and presents no significant risk to health or the environment." For a discussion of NIH efforts in risk assessment, see part III of this document and the Environmental Impact Assessment (Appendix I).

The Guidelines now reflect these roles and relationships in detail and identify all of the responsibilities in cross-reference on the other sections of the Guidelines and to the Administrative Practices Supplement. As indicated above, opportunities are afforded for public access and participation, with formal procedural requirements based on the significance of the discretionary authority. In light of these procedures, hearings by the Director's Advisory Committee may be unnecessary; but if circumstances warrant, the committee can play an oversight role as it has done in the past.

Recombinant Advisory Committee Membership. The correspondents and

witnesses at the September 15 hearing who commented on process considerations also expressed opinions on membership of the Recombinant DNA Advisory Committee (RAC). A number of recommendations were made concerning representation. Some witnesses at the September 15 hearing urged that representatives from the regulatory agencies, such as the Environmental Protection Agency, the Food and Drug Administration, and the Occupational Safety and Health Administration, have full voting membership on the RAC. It was also suggested that a representative from the Council on Environmental Quality serve on the committee. The view was expressed that the representation of these agencies on the Federal Interagency Advisory Committee on Recombinant DNA Research could not substitute for their full participation on the RAC. And it was suggested that representatives from the regulatory agencies constitute a subcommittee of the RAC for purposes of considering all future modifications of part IV.

Some Federal agency commentators suggested that representatives from research agencies such as the National Science Foundation, the Department of Agriculture, and the Veterans Administration serve on the RAC, and perhaps be permitted to consider exceptions to the prohibitions in the Guidelines.

Several commentators recommended that representatives from unions and public interest groups serve on the committee. Quotas for membership were also suggested for public interest groups, unions, and nonprofessional laboratory workers. Public interest members might also be permitted to consider exemptions and exceptions to the prohibitions.

There were a number of recommendations concerning professional and scientific expertise. One commentator advocated representation from "knowledgeable specialists in environmental processes and effects on ecosystems and their biota." Other recommended that the committee include scientists from Federal research agencies, scientists critical of the guidelines, and experts in epidemiology, medical microbiology, and clinical infectious disease research. And finally, it was suggested that RAC be advisory to the Department rather than to NIH.

Many of these concerns were raised at the December 1977 meeting of the Director's Advisory Committee (DAC) by witnesses commenting on the revised Guidelines as proposed by the RAC. As I stated in addressing those concerns in my July 28, Decision, I am acutely aware of the need for broad representation on the RAC, and this

was considered in the selection of new members.

To ensure fairness, however, nominations for openings on the RAC are publicly and widely solicited. In July 1978 a notice was filed in the *FEDERAL REGISTER* requesting public recommendations for RAC membership. All nominations are considered in selecting members of the committee. This open nomination process will be repeated annually, and thus NIH will not be the only source of RAC nominations. Further, nominations are being solicited from all agencies represented on the Federal Interagency Advisory Committee.

There was considerable discussion by the DHEW Committee about the membership of the RAC. The present RAC has 16 members, 2 of whom are lay persons. The DHEW Committee agreed that the composition should reflect the requirements set for the IBCs at the local level. Thus, it is required that at least 20 percent of the RAC members shall be persons knowledgeable about such matters as applicable law, standards of professional conduct and practice, public and occupational health, and environmental safety. In addition, it is recommended that one member be a "nondoctoral" person from a laboratory technical staff.

It was also agreed that the scientific representation on the committee should be broadly based to include persons knowledgeable in recombinant DNA technology and biological safety, but also with expertise in the broader disciplines of biology and medicine—i.e., microbiology, molecular biology, botany, ecology, virology, genetics, infectious disease, plant pathology, and epidemiology.

In view of the expanding role and responsibilities of the RAC, it was though appropriate to augment the expertise and representation. Under a new chapter, the RAC will be expanded to 20 members.

In addition, all Federal agencies represented on the Federal Interagency Advisory Committee will have nonvoting members on the RAC. (At present, some research agencies already have liaison members, such as the National Science Foundation and the Department of Agriculture.) These representatives will be nonvoting because of the large number of Federal agencies involved, but they will be participating members encouraged and enabled to present their agencies' concerns on scientific and other issues.

All members of the RAC may participate on the several subcommittees of the full committee. Thus, there is clearly no need to mandate the nature, structure, or function of subcommittees created by the chairperson in consultation with committee members. Finally, the RAC is advisory to the Sec-

retary of HEW and the Assistant Secretary for Health, as well as to the Director, NIH.

Pending the expansion and restructuring of the RAC, no changes will be made in these Guidelines and no decisions will be made requiring the RAC's prior review and advice.

Federal Interagency Advisory Committee and Recombinant DNA Research. A meeting of the Federal Interagency Advisory Committee and Recombinant DNA Research was held on October 12, 1978, to consider agency comments on the proposed revised Guidelines and proposed roles for the committee. Several agency representatives noted that under the discretion granted in the Guidelines, cognizance should be taken of Federal agency roles. Enhancement of the roles for Federal agencies other than NIH was discussed with the committee. This included the proposal of non-voting membership on the RAC, as noted above, and nominations from the agencies for potential voting members. As defined under the new procedures promulgated in part IV, all Federal agencies through their members will have an opportunity to participate in the RAC proceedings and may file written comments concerning RAC activities. Interagency Advisory Committee members will receive RAC agendas and FEDERAL REGISTER notices.

In additions to participating in the proceedings of the RAC, all agencies represented on the Federal Interagency Advisory Committee are now afforded an opportunity to request a meeting of that committee to consider RAC actions in light of their concerns. Some RAC actions, like a recommendation to release recombinant organisms into the environment, will undoubtedly necessitate a meeting of the Interagency Advisory Committee to provide information and seek consensus. Periodic meetings of this committee will also continue to be held for evaluation of recombinant technologies and their regulation under the Guidelines. (For reference, a list of the agencies represented on the Interagency Advisory Committee is presented in Appendix II.)

Scientific Counselors for ORDA

ORDA will provide consultation to Federal agencies regarding the Guidelines, and a board of scientific counselors from all Federal agencies that support or conduct recombinant DNA work will advise ORDA on the activities of the Office of the Director, ORDA, and the RAC. A key task for the board will be to ensure a common registry of all federally funded recombinant DNA research.

The DHEW Committee expressed the wish that Federal cooperation continue, and strongly endorsed the new

responsibilities of the Federal agencies under the revised Guidelines.

RESPONSIBILITIES OF NIH (SPECIFIC)

Office of the Director

The principal issues here relate to the standards and procedures for governing the discretion of the NIH Director under the Guidelines. All of the responsibilities that the Guidelines assign to the Director are now grouped under "general responsibilities" (for promulgating rules and overseeing implementation of the Guidelines) and "specific responsibilities," which include the opportunity for public and Federal agency comments. This new organization clearly delineates the responsibilities and the procedures and standards to govern the exercise of discretion based on the advice of the RAC and ORDA.

The DHEW Committee discussed the need for periodic review and assessment of NIH's experience in conducting and supporting recombinant DNA research. Accordingly, it was agreed that appropriate language should be inserted in the Guidelines that the Director, at the end of 36 months from their implementation, will report on the Guidelines and NIH experience under them in consultation with the RAC and the Federal Interagency Committee. He will solicit public comment on the draft before transmitting the final report with response to comments to the Assistant Secretary for Health and the Secretary, HEW.

In addition, the Director is now responsible for supporting training programs in laboratory safety for IBC members, Biological Safety Officers, Principal Investigators, and laboratory staff.

Recombinant Advisory Committee

A major concern of the witnesses at the September 15 hearing, and of the commentators on the proposed revised Guidelines, was related to the composition of the RAC, as discussed above. The new procedures clearly guide the discretion of the committee and provide for full public and Federal agency participation. The responsibilities of the RAC have been enhanced, with full access to the public and the Federal agencies. As I stated in my Decision of July 1978 accompanying the proposed Guidelines, the task for all RAC members has been enormous and their work and spirit of cooperation have been exemplary. I look forward to continued cooperation with Dr. Jane Setlow, Chairman, and all of the committee members. Their assistance is vital to the integrity of this research under the Guidelines.

Office of Recombinant DNA Activities

The majority of comments concerning ORDA focused on the office's oversight responsibility. The issues concerning delegation of authority to the IBC's and the role of ORDA in registering not only recombinant DNA activities but other data relating to health surveillance have been discussed in the previous section on local institutions.

There were several comments concerning the need for increased staffing for ORDA to meet the new responsibilities under the Guidelines. Additional staff has been provided, and there will be need for more in light of the new responsibilities of the Recombinant Advisory Committee to solicit public and Federal agencies' comments.

As noted previously in the section on the Interagency Committee, a board of scientific counselors from the other Federal agencies that conduct or support recombinant DNA research will be established as advisory to ORDA. This board is created in response to suggestions from Federal agencies for some mechanism to ensure uniformity in interpretations and determinations made under the Guidelines where discretion is granted. An early task of the board will be to assist in creating and maintaining a registry for all recombinant DNA activities funded by the Federal Government. The board will also assist ORDA's Director in forwarding to the RAC all requests from other Federal research agencies for action on such matters as certification of new host-vector systems. We are, in fact, trying to ensure a capability for uniform interpretation and implementation of the Guidelines throughout the Federal sector.

Another commentator urged that a time-frame be set for implementing the new standards and procedures. This request is a most important one. In anticipation of the release of the Guidelines, procedures have been drawn up for meeting the new requirements. Dr. William Gartland, Director of ORDA, has sent a letter to all institutions, IBC chairmen, and Principal Investigators, specifying the measures to be taken within the next three months to implement the new Guidelines effectively.

Registration. Here the principal comments came from the Federal agencies and private industry. The proposed revised Guidelines require the institutions that receive NIH funds for recombinant DNA research to register all recombinant DNA projects, irrespective of the source of funding. Representatives from Federal research agencies pointed out that institutions should not be required to register with NIH if they are already registering with the Federal agency that supports the work. Accordingly,

the Guidelines now specify that an institution need not register with NIH its projects funded by another Federal agency when that agency maintains a registry and provides the NIH with essential information. The institution will register projects directly with NIH if the supporting Federal agency does not choose to maintain its own registry.

At a meeting held with the DHEW Committee, representatives of the Pharmaceutical Manufacturers Association urged greater protection for proprietary and patent information under the Guidelines. The proposed revised Guidelines offered a system of voluntary registration and certification for the private sector which was not available under the 1976 Guidelines. In addition, a representative from the Commerce Department also urged expansion of the Guidelines to protect proprietary and patent information. On the other hand, environmental interest groups have expressed concern that there be maximum disclosure of information. Because of the complexity of the issue, and the general perception that NIH does not have the powers to completely protect proprietary rights and trade secrets, this aspect of the Guidelines will be handled separately after their issuance. The Food and Drug Administration is now considering issuing regulations that would require drug companies to comply with the NIH Guidelines.

Compliance. Several of the commentators and witnesses at the September 15 hearing recommended stronger language in the Guidelines concerning compliance with the Guideline provisions. The proposed revision stated that noncompliance may result in suspension, limitation, or termination of financial assistance. Several commentators urged that the language be made mandatory. Others suggested that possible violations be ranked, with definite penalties set in each case, including criminal penalties. Still others urged invocation of Section 361 of the PHS Act to ensure compliance through regulation.

Many of these issues were raised at the December hearing of the Director's Advisory Committee and in correspondence on the Guidelines as proposed by the RAC. In response to the suggestions, a section on compliance was included in the proposed revision. However, as I noted in my Decision accompanying that publication, NIH has no authority to impose fines in the absence of new legislation. I also noted that appropriate HEW procedures will be followed should suspension or termination of a grant be necessary. In light of the lack of statutory authority, penalties for negligence and criminal penalties should not be specified. It has been suggested that NIH might

seek reimbursement for any funds expended upon activities not conducted in accordance with contractual assurances. This recommendation differs from current HEW grant policy and will require much more consideration.

On the basis of DHEW Committee discussion, a new provision will allow NIH to require prior approval of any and all recombinant DNA research projects if the institution fails to comply with the Guidelines.

Invocation of Section 361 of the Public Health Act has been carefully considered by the Interagency Committee and the Department over the past two years. The most recent expression of interest in this authority was in a letter six Senators requesting Secretary Califano to consider invoking Section 361 to regulate recombinant DNA research. The letter and the Secretary's response are included in Appendix III to this Decision. Briefly, the Secretary said that the Department does not intend to evoke existing statutory authorities to regulate recombinant DNA activities at this time. He went on to quote the Interagency Committee's report of March 15, 1977, dealing with elements for legislation, including the determination that Section 361 would require a reasonable basis for concluding that recombinant DNA research may cause human disease. Such a conclusion is tenuous at best and would at present be an inappropriate basis for invoking the regulation. The Secretary, however, noted in his letter that if the Department had to act speedily, Section 361 is available and would be used. In the Secretary's view, only legislation would justify establishing regulations.

V. FOOTNOTES AND REFERENCES

In reply to correspondents' suggestions and NIH review, minor changes have been made in Footnotes 3 and 5; and five new footnotes—2A, 19A, 33A, 33B, and 37A—have been added.

A correspondent recommended that text be added to Footnote 2 to discuss the basis for allowing cloning of genetic information from *Vesicular stomatitis virus* and moderate-risk oncogenic viruses. Since Footnote 2 already refers the reader to the July 28, 1978, Decision document, where this is discussed in detail, no further discussion in Footnote 2 seems necessary.

APPENDIX A

(Director's Decision concerning Appendix A of the Guidelines)

There were many comments concerning the list of exchangers in Appendix A to be exempted from the Guidelines under Exemption I-E-4.

Some correspondents recommended additions to the list, including *Caulobacter crescentus*, *Agrobacterium*, *Proteus*, and *Xanthomonas*.

On the other hand, some correspondents felt that there was insufficient documentation for the entries on the list and that the list should be by species, not genus.

One correspondent recommended citing Bergey's *Manual of Determinative Bacteriology*. Another wrote, "It is also questionable why one should list *Escherichia coli* exchangers and not others in nature such as the organisms that exchange with *Bacillus subtilis*, with *Haemophilus influenzae*, with *Neisseria gonorrhoeae*, etc."

In response to the many comments received, the list of organisms to be exempted from the Guidelines under Exemption I-E-4 has been carefully reconsidered. The discussion below attempts to make more explicit the considerations used in constructing this list. In addition, the criteria for inclusion on the list have been tightened, reducing the list considerably and thus exempting fewer experiments from the Guidelines. References supporting the entries to the list are given below (refs. 1-22). The final list (Appendix A) closely resembles the "first list" described in Appendix D to the July 28, 1978, Environmental Impact Assessment.

It should be emphasized that the evolution of this list will continue as more experiments are done and as we gain more knowledge in this rapidly advancing field. In addition, other organisms recommended by some of the commentators (*Bacillus* or *Haemophilus* species, for instance) are currently being considered by the RAC for future inclusion under this exemption.

As noted in Appendix D to the July 28, 1978, Environmental Impact Assessment: "The natural transfer of genes between bacteria occurs by transduction (bacterial virus-mediated), transformation (uptake of isolated DNA by a bacterial cell), or conjugation (plasmid-mediated transfer of genes between bacteria requiring cell-to-cell contact). A reasonable generalization is that virtually all closely related species of bacteria can exchange genes by transduction and transformation, the former limited by the relatively narrow host-range of transducing bacteriophage and the latter by the requirement, in the case of chromosomal DNA, for homology of DNA in most recombination events. Conjugal mating with exchange of DNA can occur between virtually all Gram-negative bacteria, including naturally occurring soil and intestinal species, when mediated by a plasmid of broad host-range (for example, the Inc P-1 group plasmids). Recently, conjugal mating has also been shown to occur between strains of certain species of *Streptococcus*, a Gram-positive organism (for example, *Streptococcus faecalis*). To date, however, conjugal mating has not been demonstrated between Gram-negative and Gram-positive bacteria."

The relatedness of different microbial species can be estimated by determining the extent of DNA homology between them or by studying the properties of different microorganisms in genetic crosses. As a general rule, organisms that show considerable homology of their nucleotide sequences under a standard set of experimental conditions have the capacity to mutually integrate chromosomal genes. For example, in the case of the *Enterobacteriaceae* family of bacteria (includes *Escherichia coli* K-12), there is both extensive DNA-DNA homology (1) and chromosomal gene exchange (2) with a reasonable correlation between the degree of DNA-DNA homology and the capacity to mutually integrate chromosomal genes.

Genetic relatedness, as indicated by a high level of DNA-DNA homology between different microorganisms, is not, however,

an absolute requirement for the exchange of chromosomal genes between bacteria. In fact chromosomal gene transfer among diverse members of the Gram-negative group of bacteria has been demonstrated where the microorganisms involved show little or no DNA-DNA homology. In these cases the exchange of chromosomal genes is promoted by a broad-host-range plasmid of the Inc P-1 incompatibility type. These plasmids mobilize the chromosomes of a wide variety of Gram-negative bacteria, incorporate segments of these chromosomes, and are capable of establishing themselves along with covalently linked chromosomal genes in a wide range of Gram-negative bacteria. (3)"

In evaluating a pair of organisms for inclusion as nonnovel exchangers, we are making an estimate of the probability that the combination of genes might have occurred naturally. If the combination is not a new one, then there should be no special hazard in creating such an organism by recombinant DNA technology. Thus we can exempt this combination from the Guidelines.

Any conclusion about exchange between organisms involves some extrapolation from the experimental data available. We have tried, in the discussion below, to make explicit these extrapolations and the scientific bases for making them. For this purpose, the types of criteria which might be taken into account in preparing a list of exchangers are divided into four categories. The first two were those used in constructing Appendix A in these final revised guidelines. All four were used in constructing a list approved by the RAC and described as the "third list" in Appendix D to the July 28, 1978, Environmental Impact Assessment.

1. *Organisms which exchange chromosomal genetic information which becomes stably integrated into the host chromosome.* This, the most stringent criterion for exchange, requires significant homology between recombining segments. Organisms which meet these criteria will therefore be closely related by DNA homology measurements (Ref. 1, 2). In addition, more than one mechanism of genetic exchange may be found (i.e., transduction and plasmid mobilization), and transfer of many different markers may be demonstrated. The major extrapolation involved in this category is the extension of data from one strain to others in the same species or genus. In the Appendix A list, most of the entries are listed as genera (*Shigella*, *Salmonella*, etc.), while the *Pseudomonas aeruginosa* species is listed. One can generalize from species to genus when there is evidence that all members of the genus behave similarly, and show extensive DNA homology. In addition, in some cases, exchange has been demonstrated in many species of the genus. The DNA homology test is convincing for *Shigella*, but not for *Pseudomonas*.

2. *Organisms which exchange chromosomal information that is not necessarily integrated into the chromosome of the recipient (for instance, transfer via F⁺ or R).* This sort of exchange can occur in the absence of extensive DNA homology between the organisms, and requires only that the plasmid and its chromosomal genes be maintained in the recipient organism.

Although two organisms meeting these criteria might not be closely related, this

type of exchange is probably the best model of a recombinant DNA experiment. In both cases, relatively small amounts of genetic information are transferred, usually in plasmid form, to an otherwise "foreign" genetic background. Therefore, it seems reasonable to accept evidence of such exchange as grounds for exemption.

Criteria 3 and 4 deal specifically with Inc P-1 plasmids, but the principles can be extended to other exchange mechanisms.

3. *Organisms which show evidence of a plausible mechanism for exchange (e.g., R⁺ formation or evidence of mobilization of chromosomal genes by an Inc P-1 plasmid.)* In this case, the plasmid itself has been shown to move from organism to organism. It has been shown to pick up chromosomal genes, but the transfer of these chromosomal genes in interspecies matings has not necessarily been demonstrated.

To endorse these criteria, we must extrapolate from the transfer within the species to more distantly related organisms. For such an extrapolation, one must assume that no barriers will exist for R⁺ transfer that do not exist for transfer of the plasmid itself. In many tested cases, this is clearly true: transfer of chromosomal genes incorporated into an R factor is comparable in frequency to transfer of the plasmid itself, and the R⁺ can be moved to a broad range of organisms (4). However, this may not be universally true (5).

4. *Organisms which can receive or donate broad host range plasmids.* Since these plasmids are known, in many cases, to mobilize the chromosome and transfer chromosomal genes, such transfer might be expected for any organism that receives or donates the plasmid. This extrapolation assumes that (i) chromosomal pickup is always able to occur with these plasmids and (ii) transfer of chromosomal genes to other species will occur (this latter case is the same as that analyzed under criterion 3).

Analysis of the basis for the first extrapolation would include consideration of the numerous cases where such mobilization and transfer can be detected (see, for instance, ref. 5-10) and those few where it cannot (11).

It is my decision that the data supporting the use of criteria 3 and 4, while suggestive, are not yet compelling enough to warrant exemption from the Guidelines for recombinant DNA experiments. As more data are accumulated, this conclusion will be carefully reconsidered.

The Issue of Two-Way Exchange

The organisms listed in appendix A fit the first two criteria described above—i.e., in all cases, there is direct evidence of chromosomal exchange between two species on the list, and many show extensive DNA homology as well. In addition, for all the organisms on this list, exchange can be demonstrated in two directions. Further, if organisms A and B both exchange genetic information (both donate and receive) with a third organism—*E. coli* K-12, for instance—then *E. coli* K-12 can act as a path for the DNA of organism A to reach B, and vice versa. Thus, the requirement for two-way exchange allows us to exempt recombinants made between A and B. Therefore, we have exempted "any recombinant DNA molecules that are (1) composed entirely of DNA segments from one or more of the organisms listed below and (2) to be propagated in any of the organisms listed below."

It would make sense, of course, to have one-way lists as well, where cloning exempt from the Guidelines would only be allowed in the recipient. The creation of such lists will be considered by the RAC.

REFERENCES

1. Brenner, D. J. (1977). *Characterization and Clinical Identification of Enterobacteriaceae by DNA Hybridization*. Progress in Clinical Pathology 7:71-118.
2. Sanderson, K. E. (1976). *Genetic Relatedness in the Family Enterobacteriaceae*. Ann. Rev. Microbiol. 30:327-349.
3. Holloway, B. W. (1978). *Plasmids Which Mobilize Bacterial Chromosomes*. Plasmid, in press.
4. Dixon, R., F. Cannon, and A. Kondorosi (1976). *Construction of a P Plasmid Carrying Nitrogen Fixation Genes From Klebsiella Pneumoniae*. Nature 260:268-271.
5. Johnston, A. W. B., S. M. Setchell, and J. E. Beringer (1978). *Interspecific Crosses Between Rhizobium leguminosarum and Rhizobium meliloti: Formation of Haploid Recombinants and of R-Primes*. J. Gen. Microbiol. 104:209-218.
6. Beringer, J. E., S. A. Hoggan, & A. W. B. Johnston (1978). *Linkage Mapping in Rhizobium Leguminosarum by Means of R Plasmid-Mediate Recombination*. J. Gen. Microbiol. 104:201-207.
7. Sistrom, W. (1977) *Transfer of Chromosomal Genes Mediated by Plasmid R68.45 in Rhodospseudomonas sphaeroides*. J. Bacteriol. 131:526-532.
8. Haas, D., and B.W. Holloway (1978). *Chromosome Mobilization by the R Plasmid R68.45: A Tool in Pseudomonas Genetics*. Mol. Gen. Genetics 158:229-237.
9. Townner, K.J. (1978). *Chromosome Mapping in Acinetobacter calcoaceticus*. J. Gen. Microbiol. 104:175-180.
10. Stanisch, V.A., and B.W. Holloway (1971). *Chromosome transfer in Pseudomonas aeruginosa Mediated by R Factors*. Genet. Res. 17:169-172.
11. Alexander, J.L., and J.D. Jollick (1977). *Transfer and expression of Pseudomonas Plasmid RPI in Caulobacter*. J. Gen. Microbiol. 99:325-331.
12. Baron, L.S., P. Gemski, E.M. Johnson, and J.A. Wohlhieter (1968). *Intergenic Bacterial Matings*. Bacter. Reviews 32:362-369.
13. Cannon, F.C., R.A. Dixon, J.R. Postgate, and S.B. Primrose (1974). *Chromosomal Integration of Klebsiella Nitrogen Fixation Genes in E. coli*. J. Gen. Microbiol. 80:227-239.
14. Chatterjee, A.K., and M.P. Starr (1973). *Gene Transmission Among Strains of Erwinia Amylovora*. J. Bact. 116:1100-1106.
15. Chatterjee, A.K. and M.P. Starr (1973). *Transmission of Lac by the Sex Factor E in Erwinia Strains from Human Clinical Sources*. Infection and Immunity 8:563-572.
16. Denarie, J., C. Rosenberg, B. Bergeron, C. Boucher, M. Michel, and M. Barate de Bertalmio (1977). *Potential of RP4:Mu Plasmids for In Vivo Genetic Engineering of Gram Negative Bacteria*. In Bukhari, A.I., J. A. Shapiro, and S.L. Adhya (editors); *DNA Insertion Elements, Plasmids and Episomes*, Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y.
17. Faelen, M., A. Toussaint, M. Van Montague, S. Vander Elsacher, G. Engler, and J. Schell (1977). *In Vivo Genetic Engineering: The Mu-Mediated Transposition of Chromosomal DNA Segments onto Transmissible Plasmids*. In Bukhari, A. I., J. A. Shapiro,

and S.L. Adhya (editors), *DNA Insertion Elements, Plasmids and Episomes*, pp. 521-530, Cold Spring Harbor Laboratory, Cold Spring Harbor, N.Y.

18. Goldberg, R. B., R. A. Bender, and S. L. Streicher (1974). *Direct Selection for Pl-Sensitive Mutants of Enteric Bacteria*. J. Bact. 118:810-814.

19. Hedges, R. W., A. E. Jacob, and I. P. Crawford (1977). *Wide Ranging Plasmid Bearing the Pseudomonas Aeruginosa Tryptophan Synthetase Genes*. Nature 267:283-284.

20. Johnson, E. M., B. P. Placek, N. J. Snellings, and L. S. Baron (1975). *Conservation of Salmonella Typhimurium Deoxyribonucleic Acid By Chromosomal Insertion in a Partially Diploid Escherichia Coli Hybrid*. J. Bact. 123:1-6.

21. Nagahari, K., Y. Sano, and K. Sakaguchi (1977). *Derepression of E. Coli trp Operon on Interfamilial Transfer*. Nature 266:745-746.

22. Signer, E. R., a. Torriani, and C. Levinthal (1961). *Gene Expression in Intergenic Merozygotes*. Cold Spring Harbor Symp., Quant. Biol. 26:31-34.

APPENDIX B

(Director's Decision concerning Appendix B of the Guidelines)

Three correspondents correctly point out that since the publication in 1974 of the "CDC Classification of Etiologic Agents on the Basis of Hazard" (which is repeated verbatim as Appendix B to the Guidelines), *Actinomyces* have been reclassified. Formerly considered to be fungal agents, they are now considered bacterial agents. An explanatory footnote has been added to the table.

APPENDIX I—ENVIRONMENTAL IMPACT ASSESSMENT

ENVIRONMENTAL IMPACT OF THE FINAL GUIDELINES

An *Environmental Impact Assessment of the NIH-Proposed Revised Guidelines (EIA)* was published with the Guidelines in the FEDERAL REGISTER of July 28, 1978. The assessment was based on an intensive analysis of the Guidelines then in effect, the Guidelines as proposed by the Recombinant DNA Advisory Committee in September 1977, and the Guidelines as proposed by NIH in July 1978. The conclusion of the assessment was that there would be no adverse impact of the NIH-proposed changes upon the environment.

The issues raised by the commentators in correspondence and by the witnesses of the September 15 hearing on the NIH-proposed revised Guidelines are reviewed in detail in the accompanying Decision document. It is the conclusion, based on that review of the alternatives proposed in July 1978 and the decisions reflected in the final Guidelines, that there will be no adverse impact of the Federal actions upon the environment. Indeed, in the extensive revision of part IV, these final Guidelines enhance public participation and accessibility at the national and local levels, with increased emphasis on health surveillance and safety training. The final Guidelines provide an even stronger framework to ensure that no significant risk is presented to the public health or the environment.

Consideration now follows of certain issues relating to the EIA of July 28,

1978, which were raised in correspondence and by witnesses at the September 15 hearing.

NEPA Considerations

A witness at the September 15 hearing cited the EIA as being inadequate and held that a full Environmental Impact Statement (EIS) should be prepared. The witness stated that an EIS is clearly required by the law. In addition, the witness found the EIA inadequate in its analysis of the revisions in such areas as exemptions and the use of *E. Coli* K-12 and other host-vector systems.

In our view, the EIA prepared by NIH on the proposed revisions to the NIH Guidelines fully satisfies the requirements of the National Environmental Policy Act of 1969 (NEPA).

The current Guidelines on Recombinant DNA Research were issued on June 23, 1976, and published in the FEDERAL REGISTER on July 7, 1976 (41 F.R. 27902). They were developed by NIH after opportunity for public comment and an open meeting at which members of the public were invited to testify (41 F.R. 2105).

In the Decision of the Director, NIH, which accompanied the 1976 Guidelines, it was indicated that NIH would prepare a draft EIS on the Guidelines in order to give the public further opportunity to comment. The draft EIS was published in the FEDERAL REGISTER on September 9, 1976, with a preamble soliciting public comment (41 F.R. 38426). After the close of the comment period, a final EIS was prepared, taking into account the comments received and scientific developments up to that time. The EIS actually became final on November 28, 1977, when notice of its receipt was published in the FEDERAL REGISTER by the Council on Environmental Quality (42 F.R. 60588).

During this period, scientific evidence has been accumulating that the risks presented by recombinant DNA research, which has always been purely speculative, were indeed remote. As a result, it became apparent that the restrictions in the Guidelines were more stringent than necessary and that the Guidelines needed to be revised. The process of revision was first undertaken by NIH's Recombinant DNA Advisory Committee (RAC), which referred a proposal for revision to the Director, NIH, in September 1977. On September 27, 1977, the Director published the RAC's proposal in the FEDERAL REGISTER for public comment (42 F.R. 49596). At the same time, and in a subsequent FEDERAL REGISTER notice (42 F.R. 59918), the Director announced a two-day meeting to secure public testimony on the RAC proposal. This meeting was held on December 15-16, 1977, and

witnesses appeared from environmental groups, the scientific community, and industry.

Based on the comments received and the testimony at the December meeting, the Director developed an NIH-proposed revision of the Guidelines (referred to herein as the PRG), relying in part on the RAC proposal. The PRG was issued by the Director, as a proposal, with the approval of the Secretary, on July 19, 1978, and published in the FEDERAL REGISTER on July 28, 1978 (43 FR 33042), the preamble to the PRG requested public comment, announced that a further hearing on the PRG would be conducted on September 15, 1978, before an HEW panel chaired by the General Counsel, and indicated that final action on the PRG would be taken after the panel had reviewed both the written comments and those provided at the hearing.*

When the PRG was published on July 28, it was accompanied by a detailed EIA, which included a discussion of the risks and benefits of recombinant DNA research and an analysis of the current Guidelines, of alternatives to the Guidelines, and of NIH's PRG. In addition to an overall assessment of the environmental impact of the PRG, separate environmental impact analyses were made of each section. The conclusions reached were summarized at the beginning of the EIA as follows:

As can best be determined from all evidence compiled to date and analyzed in numerous scientific and public forums, there will be no adverse environmental impact from recombinant DNA research conducted under the Director's proposed revisions. The Environmental Impact Statement on NIH Guidelines for Research Involving Recombinant DNA Molecules, issued in October 1977, predicted that the environmental impact of research conducted under the 1976 NIH Guidelines would be the continued protection of the laboratory worker, the general public, and the environment from conjectural hazards. So far, this prediction has been confirmed: We know of no scientists conducting recombinant DNA research in the United States or other countries who are not following the NIH or comparable guidelines, and no untoward effect of the research has been reported. Meanwhile, new scientific evidence as well as extensive experience in operating under the NIH Guidelines indicate that revisions are in order. The predictable effect of continued use of recombinant DNA techniques under the Director's proposed revisions would be a greater realization of the benefits of this valuable tool without compromise of safety. (43 FR 33006).

The EIA prepared by NIH on the PRG discusses in detail scientific developments regarding recombinant DNA research. It justifies the changes proposed by NIH, explains why some RAC and public proposals were not ac-

* More than 30 persons from environmental groups and the scientific community testified at the September 15 hearing.

RISK ASSESSMENT

cepted, and assesses at some length the anticipated environmental effects of the changes NIH proposed to make.

In my view the EIA represents a conscientious, thoughtful, and thorough effort to carry out our responsibilities under NEPA. As one correspondent noted, the assessment is a "thorough and fully documented analysis . . . that describes the technical aspects of this research and its conjectural risks and benefits." The EIA took a "hard look" at the current Guidelines, the various alternatives, and the environmental implications of the proposed changes. By soliciting public comment and conducting a public hearing, relevant areas of environmental concern were identified. I believe that a convincing case is made in the EIA that the proposed changes would have no significant environmental impact.

My Decision accompanying these final Guidelines reviews at some length exemptions from the Guidelines in light of the comments made by correspondents and witnesses. And indeed, a lengthy analysis of the list of exempt organisms in Appendix A documents the prudence and caution in which NIH is proceeding. On the basis of comments, the list has been modified and the scope of experiments restricted.

It was also asserted by witnesses that the filing of an EIS would provide for public input in the Government's decisions affecting the environment. In my view, NIH's overall response to the issues raised by recombinant DNA research has been to ensure a full public hearing of all issues. When these issues first arose, NIH conducted public hearings, solicited public comment, developed Guidelines, and published an EIS, which ultimately received judicial approval.

Since that time scientific evidence has shown that the initial concerns about the hazards of this research may have been exaggerated. Accordingly, we proposed to relax some aspects of the Guidelines. In doing so, we again conducted hearings and solicited public comment. And the NIH-proposed revised Guidelines were published for comment, followed by a hearing under the aegis of a DHEW committee chaired by Peter Libassi, the DHEW General Counsel. In addition, all of the proceedings and all documents have been published in an ongoing series of volumes that document the basis for NIH policies. The documents contain relevant proceedings of the executive, legislative, and judicial branches. A fourth volume will be published in January containing the transcript of the September 15, 1978, hearing, all correspondence received by NIH commenting on the proposed Guidelines of July 28, 1978, and all other relevant documents.

Several witnesses raised issues concerning the concepts of risk and safety as outlined in the Environmental Impact Assessment (EIA). One witness emphasized the concept of risk as "a relatively objective measurement of hazards" and safety as "a subjective expression of the level of risk which is acceptable to a population." He believes the NIH Guidelines and Assessment confuse these two concepts. The Guidelines, in his view, do not provide adequate institutional mechanisms to ensure that the value issues involved in safety are thoroughly aired by the general public. Thus, because safety is "value-laden, subjective, and in a sense, political," the Guidelines must reflect these values by ensuring adequate mechanisms for determining safety standards and their implementation.

The October 1977 EIS on the original NIH Guidelines and the July 1978 EIA on the proposed revisions address in great detail occupational and environmental health and safety concerns. As noted in the EIA (FEDERAL REGISTER, p. 33131, middle column), several changes are proposed in the revised Guidelines "in the implementation, review, and monitoring of recombinant DNA activities at the local and national levels, to insure appropriate safety practices and procedures that would minimize any significant environmental impact."

These modifications focus on a restructuring of roles and responsibilities. The applicability of the Guidelines has been extended to all recombinant DNA research at institutions that receive any recombinant DNA research support from NIH. Biosafety committees have been given broader responsibilities. At the request of several commentators, Appendix D to the original Guidelines has been revised and updated as *Laboratory Safety Monograph—A Supplement to the NIH Guidelines*. The monograph is a compendium of useful safety information, including instructions on emergency procedures, laboratory techniques for biohazard control, and decontamination and disposal methods. It provides much detail on the responsibilities of the local institution for safety practices and procedures. The impact of these actions and the restructuring of part IV of the Guidelines will be the promotion of safer conduct of this research, affording a greater measure of protection to the environment, with emphasis on occupational health and safety.

Several commentators also urged NIH to initiate and fund a comprehensive risk-assessment program to provide a scientific basis for defining appropriate containment requirements for recombinant DNA experiments.

The DHEW Committee reviewed NIH efforts in this regard. It was noted that recombinant DNA research experiments provide a great deal of information on risks. In addition, NIH is supporting a number of studies in risk assessment. The participants at the Falmouth Conference* recommend studies in six areas, and NIH is following up on those recommendations.

The Rowe-Martin polyoma experiments are discussed in the Decision Document. In addition, intramural NIH scientists are collaborating with scientists from other institutions in testing the virulence in mice of *E. coli* K-12 containing "shotgun clones" of recombinant DNA derived from other species.

A number of contractors of the National Institute of Allergy and Infectious Diseases are testing the biological containment capabilities of various derivatives of *E. coli* K-12. Some are testing the survival and capacity of plasmid and phase vectors to be transmitted to secondary bacterial hosts in the gastrointestinal tract of man and mouse. Others are assessing these parameters in model sewage treatment systems and in situations simulating accidental spills and other types of accidental release of the organisms for experimental procedures.

In addition, investigators proposing systems to be certified by NIH as HV1 or HV2 must perform certain specified tests on these systems relevant to their survival and transmission properties. It is also anticipated that if investigators seek exceptions to the prohibitions for specified clones, NIH will request substantial risk-assessment experiments to be performed to evaluate claims of safety.

Another commentator noted that Dr. Sidney Brenner of the Medical Research Council's Laboratory for Molecular Biology in Cambridge, England, had stated that he believed the whole method of risk-assessment up to now is "fragmentary" and that what is needed is a "more systematic approach," which he was trying to take. Dr. Brenner, when asked for more information on his studies, explained that the method of risk-assessment he referred to is not a new experimental approach but a new analytical approach. Dr. Brenner's work will be followed closely for any new information that sheds light on potential risks or safety of experiments under the Guidelines.

SOCIAL ETHICS

A witness at the September 15th hearing noted that "the steps taken to insure containment are of great immediate importance and the present guidelines should be continued." But

*See Journal of Infectious Diseases, 137:704-708, May 1978

he stated that "ultimately the discussion, kinds of facility and guidelines are simply irrelevant." In his view, human security may be threatened by "the biologic revolution." He notes that just as the "nuclear reality" has led to the term "omnicide," and environmental pollution to "ecocide," biological research may lead to "genecide."

As noted in my Decision document (FEDERAL REGISTER, July 28, 1978), NIH has been asked to provide a forum for dealing with social issues relating to "genetic engineering." The concerns of this witness may be taken in the same context. My Decision notes that NIH has been addressing the policy questions involving the safety of this research, not the "potential future application *** to the altering of the genetic character of higher forms of life, including man ***." In light of public concern, a study is warranted of the ethical, legal, and social implications of these techniques. The National Commission for Protection of Human Subjects of Biomedical and Behavioral Research considered, but was unable to initiate, a study ***. Such a study might be considered by the Department's newly created Ethical Advisory Board. It could also be a key priority for the National Commission for the Protection of Human Subjects, which was reauthorized by the Congress before adjournment of this session.

APPENDIX II—FEDERAL INTERAGENCY ADVISORY COMMITTEE ON RECOMBINANT DNA RESEARCH, OCTOBER 1978

DEPARTMENT OF AGRICULTURE

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APPENDIX III

EXCHANGE OF LETTERS BETWEEN SENATORS AND SECRETARY CALIFANO

[Letter to Senator Kennedy attached; similar letters were sent to the five other Senators]

UNITED STATES SENATE,

Washington, D.C., June 1, 1978

HON. JOSEPH A. CALIFANO, JR.,

Secretary of Health, Education and Welfare, Department of Health, Education and Welfare, Washington, D.C. 20201.

DEAR MR. SECRETARY: Since 1976 four committees of the House and Senate have held nine series of hearings to consider the issues relating to recombinant DNA research. These extended and thorough inquiries have shown that, with respect to the research they support and conduct, the National Institutes of Health have taken a properly cautious approach by prohibiting certain presumably hazardous experiments, requiring certification of the safety of host-vector systems, prescribing physical and biological containment measures for the con-

duct of permissible experiments, and providing for changes in these restrictions as further scientific evidence resolves the uncertainties about the health and environmental effects of using recombinant DNA techniques.

Evidence accumulated in the past year, rather than revealing any hazards associated with these experiments, points to a high level of safety in the use of the predominant host organism, the K-12 strain of *E. coli*. The NIH Recombinant DNA Molecule Program Advisory Committee has recommended changes in the Institute's research guidelines to reflect this evidence, and these recommendations are being considered by Director Fredrickson. Other hosts and vectors have received less scrutiny, and uncertainty remains about risks that may be associated with future applications of the technology. These uncertainties justify continuing to require certain precautions in recombinant DNA work.

However, the hearings have also underscored the need to correct deficiencies in the present system of regulation. Privately supported research activities are not subject to monitoring by NIH nor to sanctions for failure to comply with the guidelines. Application of the NIH standards by other Federal agencies is voluntary. As Director Fredrickson has stated on several occasions, it is doubtful this enforcement by the principal Federal sponsor of recombinant DNA research—NIH—is appropriate. Procedures for revising the standards and exempting certain experiments should be clarified. It is important to ensure the accountability of institutions and investigators, particularly if they are to assume greater responsibility for monitoring compliance. The Federal Government should anticipate commercial applications of recombinant DNA techniques and the concerns they are likely to raise.

In view of these developments and in view of the heavy legislative schedule of the Senate and the Human Resources Committee, we are writing to inquire whether the deficiencies in the present regulatory system can be remedied through executive action in the event final agreement on legislation is not possible. Specifically, it would seem possible to shift monitoring and enforcement responsibilities from NIH to a more appropriate agency within the Department of Health, Education, and Welfare. It would also seem possible to remedy the problems of accountability and of coverage in the process of revising the recombinant DNA guidelines. On the basis of the survey of existing statutory authorities conducted by the Committee on Commerce, Science and Transportation, there seems to be adequate authority to regulate the commercial application of products developed through recombinant DNA technology. There is, however, need for more effective coordination among Federal agencies in the implementation of these authorities.

In this regard, you expressed to Senator Stevenson in your letter of February 27, 1978, that the Food and Drug Administration "... could, under existing authority, require any firm seeking approval of a product which may be the end product of recombinant DNA research to certify to the Agency that it has complied with the NIH guidelines on recombinant DNA." You noted also that FDA has authority to inspect firms making such certification to assure compliance with the NIH guidelines. This statement is important because most,

if not all, recombinant DNA research by the private sector is being conducted by pharmaceutical companies with the objective of developing products that would be marketed in accordance with FDA regulations. A decision by the Administration to use this existing authority would bring the large majority of privately funded recombinant DNA research activities under the NIH guidelines. Is the Administration prepared to use the authority cited in your February 27th letter?

Finally, it has been suggested that section 361 of the Public Health Service Act provides sufficient authority to promulgate regulations covering recombinant DNA research conducted by the private sector with non-Federal funds. Although you have expressed the view that specific legislative authority is preferable to using the authority of section 361, we are raising the issue again for three reasons: (1) The need for new legislation is less clear than it was one year ago when the initial bills were introduced, (2) the existing regulatory deficiencies relating to Federally-supported research can be remedied by executive action, and (3) the heavy legislative schedule may preclude action in this session of Congress. In view of these developments, it seems prudent to explore the willingness of the Executive Branch to use the authority of section 361 to cover privately-funded recombinant DNA research. In addition, we request that you solicit a legal opinion from the Department of Justice as to the use of section 361 in this manner.

There is an additional factor to consider. In the past, Congress has been reluctant to extend statutory control over a specific field of scientific investigation unless such authority was absolutely necessary to protect the public's health and safety. In view of the scientific evidence accumulated during the past year, it is not possible to reach this conclusion in the case of recombinant DNA research. If the deficiencies discussed above could be corrected through executive action—by use of existing powers of FDA and/or the authority of section 361—there would be no reason to legislate new statutory controls.

In the event these executive actions were implemented, we would recommend that an appropriate group of experts and lay persons, such as the advisory committee to the NIH Director, continue to monitor the scientific evidence relating to the hypothetical risks of recombinant DNA research. If evidence indicating actual risks were to be developed, Congress could once again consider the need for legislation.

Since we are presently considering the legislative agenda for the balance of this session, we would appreciate your prompt response to this inquiry.

Sincerely,

EDWARD M. KENNEDY,
*Chairman, Subcommittee on
Health and Scientific
Research.*

JACOB K. JAVITS,
*Ranking Minority Member,
Committee on Human Resources.*

GAYLORD NELSON,
*Member,
Committee on Human Resources.*

ADLAI E. STEVENSON,
*Chairman, Subcommittee on
Science,
Technology and Space.*

HARRISON A. WILLIAMS, JR.,
*Chairman,
Committee on Human Resources.*

RICHARD S. SCHWEIKER,
*Ranking Minority Member, Sub-
committee on Health and Sci-
entific Research.*

THE SECRETARY OF HEALTH,
EDUCATION, AND WELFARE,
Washington, D.C. September 12, 1978.
HON. EDWARD M. KENNEDY,
*Chairman, Subcommittee on Health and
Scientific Research, Committee on
Human Resources, United States Senate,
Washington, D.C. 20510*

DEAR TED: Thank you for your letter in which you have raised a number of thoughtful questions concerning the need for legislation to regulate recombinant DNA research.

As you state in your letter, new scientific information, particularly on the safety of *E. coli* K-12 (the principal organism used in these experiments), indicates that extensive regulation in this research area may be unwarranted. Indeed, there is additional evidence that many recombinant DNA manipulations in the laboratory may be similar to events that occur in nature.

In view of these scientific developments, you raise the question as to whether legislation is necessary or whether existing statutory authority would be sufficient for purposes of regulation. You cite specifically the regulatory authority of the FDA and of the Public Health Service Act (Section 361).

The Department does not intend to invoke existing statutory authorities to regulate DNA activities at this time. If an emergency were to occur before passage of legislation, the Department could reconsider this position in order to take action on an interim basis. But, we continue to support legislation if it embodies the moderate approach of H.R. 11192. The virtue of such legislation is that it may include a number of specific provisions that permit useful flexibility in implementing regulations. Such provisions include:

- the promotion of uniform national standards,
- clear authority for the Secretary in relationship to other Federal laws,
- avoidance of normal administrative procedures for initial application of NIH Guidelines and waiver of the Administrative Procedures Act (APA) for issuance of administrative regulations, and authority for the Secretary to waive regulatory requirements for activities that pose no significant risk to health or the environment.

In recommending legislation, the Federal Interagency Committee on Recombinant DNA Research reviewed all existing statutory authority and found that none could provide for comprehensive regulation of these activities. The Interagency Committee noted that under Section 361 "there would presumably have to be a reasonable basis for concluding that the products of all re-

combinant DNA research cause or may cause human disease. Such a conclusion would undoubtedly be tenuous at best, and it is unlikely that resulting requirements could be effectively imposed and enforced."

Your letter suggested that we seek a legal opinion from the Department of Justice on the use of Section 361. Justice is represented in the Interagency Committee and has participated in the review and recommendations concerning existing statutory authorities, including Section 361.

The authorities of the Food and Drug Administration (FDA) were reviewed by the Committee; but inasmuch as recombinant DNA research has not yet reached the stage where it has yielded products to be regulated by FDA, it was agreed that FDA probably does not have authority to impose requirements on such research at present.

On July 28, the Department published proposed revisions to the Guidelines on recombinant DNA research for 60 days of comment. In addition, I have asked General Counsel Peter Libassi to serve as Chairman and Dr. Donald Fredrickson as Vice Chairman of a September 15 public hearing on these proposed revisions. Analysis of written and oral comments will proceed as quickly as possible, with final issuance of the revised Guidelines expected before the first of December.

A number of proposed changes in the Guidelines would permit, on a voluntary

basis, registration of activities and NIH certification of new host-vector systems from the private sector. Protection would be provided for proprietary patent information for these private sector activities. Registration of recombinant DNA projects, irrespective of source of funding, would be required of institutions receiving NIH support for recombinant DNA research. By these means, a national registry of all Federal and private sector activities may evolve.

The Interagency Committee has been an invaluable forum for developing coherent and coordinated policies through the representation of all the relevant research and regulatory agencies, and has served to ensure a commonality of standards. This Committee should continue to provide such oversight for the development of Federal policies and to ensure institutional compliance with the NIH Guidelines. Other advisory committees, both technical and public, must continue. The Recombinant DNA Advisory Committee will have a continuing role, and as you suggest in your letter, the public Advisory Committee to the Director, NIH, should continue to consider recommendations from the technical group.

The NIH and the Center for Disease Control (CDC) will continue to work closely as they have done over the past 18 months concerning safety aspects of the Guidelines. For example, NIH, in conjunction with CDC, has been developing mechanisms for assisting institutions in managing possible

laboratory emergencies and for providing direct assistance when appropriate. Indeed, NIH and CDC are collaborating in a revision of the CDC Classification of Etiologic Agents on the Basis of Hazards—a classification that underpins some of the safety requirements of the Guidelines. Also, these agencies are reviewing packaging and shipping requirements relevant to recombinant DNA activities.

Close cooperation and consultation with the Food and Drug Administration and the Environmental Protection Agency will also be essential, since the regulatory authority of these agencies will come into play when recombinant DNA research inventions are ready for commercial development. The Occupational Safety and Health Administration will exercise its regulatory authority in the workplace.

We are pleased with the progress made in the absence of legislation and believe that invocation of existing authorities, however appropriate, would not contribute materially to our objectives. Only passage of legislation embodying the features cited here would, in our opinion, justify the change from a voluntary to a regulatory approach. Should the Senate choose to act, I would strongly urge adoption of an approach similar to H.R. 11192.

Sincerely,

JOSEPH A. CALIFANO, Jr.

[FR Doc. 78-35532 Filed 12-21-78; 8:45 am]

revised paper

FRIDAY, DECEMBER 22, 1978

PART VII



**DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE**

**National Institutes of
Health**



**GUIDELINES FOR
RESEARCH INVOLVING
RECOMBINANT DNA
MOLECULES**

[4110-08-M]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

National Institutes of Health

GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

DECEMBER 1978.

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I. SCOPE OF THE GUIDELINES

I-A. Purpose. The purpose of these Guidelines is to specify practices for constructing and handling (i) recombinant DNA molecules and (ii) organisms and viruses containing recombinant DNA molecules.

I-B. Definition of Recombinant DNA Molecules. In the context of these Guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from

the replication of those described in (i) above.

I-C. General Applicability. See Section IV-B.

I-D. Prohibitions. The following experiments are not to be initiated at the present time:

I-D-1. Formation of recombinant DNAs derived from the pathogenic organisms classified [1] as Class 3, 4, or 5 [2] or from cells known [2A] to be infected with such agents, regardless of the host-vector system used.

I-D-2. Deliberate formation of recombinant DNAs containing genes for the biosynthesis of toxins potent for vertebrates [2A] (e.g., botulinum or diphtheria toxins; venoms from insects, snakes, etc.).

I-D-3. Deliberate creation by the use of recombinant DNA of a plant pathogen with increased virulence and host range beyond that which occurs by natural genetic exchange. [2A]

I-D-4. Deliberate release into the environment of any organism containing recombinant DNA.

I-D-5. Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally, if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture. [2A]

I-D-6. Large-scale experiments (e.g., more than 10 liters of culture) with organisms containing recombinant DNAs, unless the recombinant DNAs are rigorously characterized and the absence of harmful sequences established [3]. (See Section IV-E-1-b-(3)-(d).)

We differentiate between small- and large-scale experiments with organisms containing recombinant DNAs because the probability of escape from containment barriers normally increases with increasing scale.

Experiments in these categories may be excepted [4] from the prohibitions (and will at that time be assigned appropriate levels of physical and biological containment) provided that these experiments are expressly approved by the Director, NIH, with advice of the Recombinant DNA Advisory Committee after appropriate notice and opportunity for public comment. (Section IV-E-1-b-(1)-(e).)

I-E. Exemptions. It must be emphasized that the following exemptions [4] are not meant to apply to experiments described in the Section I-D-1 to I-D-5 as being prohibited.

The following recombinant DNA molecules are exempt from these Guidelines, and no registration with NIH is necessary:

I-E-1. Those that are not in organisms or viruses. [5]

I-E-2. Those that consist entirely of DNA segments from a single nonchromosomal or viral DNA source, though

one or more of the segments may be a synthetic equivalent.

I-E-3. Those that consist entirely of DNA from a prokaryotic host, including its indigenous plasmids or viruses, when propagated only in that host (or closely related strain of the same species) or when transferred to another host by well-established physiological means; also those that consist entirely of DNA from a eukaryotic host, including its chloroplasts, mitochondria, or plasmids (but excluding viruses), when propagated only in that host (or a closely related strain of the same species).

I-E-4. Certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the Director, NIH, with advice of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment. (See Section IV-E-1-b-(1)-(d).) Certain classes are exempt as of publication of these Revised Guidelines. The list is in Appendix A. An updated list may be obtained from the Office of Recombinant DNA Activities, National Institutes of Health, Bethesda, Maryland 20014.

I-E-5. Other classes of recombinant DNA molecules, if the Director, NIH, with advice of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment, finds that they do not present a significant risk to health or the environment. (See Section IV-E-1-b-(1)-(d).)

I-F. General Definitions. See Section IV-C.

II. CONTAINMENT

Effective biological safety programs have been operative in a variety of laboratories for many years. Considerable information therefore already exists for the design of physical containment facilities and the selection of laboratory procedures applicable to organisms carrying recombinant DNAs. [6-19] The existing programs rely upon mechanisms that, for convenience, can be divided into two categories: (i) A set of standard practices that are generally used in microbiological laboratories, and (ii) special procedures, equipment, and laboratory installations that provide physical barriers which are applied in varying degrees according to the estimated biohazard.

Experiments on recombinant DNAs, by their very nature, lend themselves to a third containment mechanism—namely, the application of highly specific biological barriers. In fact, natural barriers do exist which limit either

(i) the infectivity of a vector, or vehicle, (plasmid or virus) for specific hosts or (ii) its dissemination and survival in the environment. The vectors that provide the means for replication of the recombinant DNAs and/or the host cells in which they replicate can be genetically designed to decrease by many orders of magnitude the probability of dissemination of recombinant DNAs outside the laboratory.

As these three means of containment are complementary, different levels of containment appropriate for experiments with different recombinants can be established by applying various combinations of the physical and biological barriers along with a constant use of the standard practices. We consider these categories of containment separately here in order that such combinations can be conveniently expressed in the Guidelines.

In constructing these Guidelines, it was necessary to define boundary conditions for the different levels of physical and biological containment and for the classes of experiments to which they apply. We recognize that these definitions do not take into account all existing and anticipated information on special procedures that will allow particular experiments to be carried out under different conditions than indicated here without affecting risk. Indeed, we urge that individual investigators devise simple and more effective containment procedures and that investigators and institutional biosafety committees recommend changes in the Guidelines to permit their use.

II-A. Standard Practices and Training. The first principle of containment is a strict adherence to good microbiological practices. [6-15] Consequently, all personnel directly or indirectly involved in experiments on recombinant DNAs must receive adequate instruction. (see Sections IV-D-1-g, IV-D-5-d and IV-D-8-b.). This shall be a minimum include instructions in aseptic techniques and in the biology of the organisms used in the experiments, so that the potential biohazards can be understood and appreciated.

Any research group working with agents with a known or potential biohazard shall have an emergency plan which describes the procedures to be followed if an accident contaminates personnel or the environment. The principal investigator must ensure that everyone in the laboratory is familiar with both the potential hazards of the work and the emergency plan. (See Sections IV-D-5-e and IV-D-3-d.) If a research group is working with a known pathogen where there is an effective vaccine it should be made available to all workers. Where serological monitoring is clearly appropriate it

shall be provided. (See Sections IV-D-1-h and IV-D-8-c.)

II-B. Physical Containment Levels. The objective of physical containment is to confine organisms containing recombinant DNA molecules, and thus to reduce the potential for exposure of the laboratory worker, persons outside of the laboratory, and the environment to organisms containing recombinant DNA molecules. Physical containment is achieved through the use of laboratory practices, containment equipment, and special laboratory design. Emphasis is placed on primary means of physical containment which are provided by laboratory practices and containment equipment. Special laboratory design provides a secondary means of protection against the accidental release of organisms outside the laboratory or to the environment. Special laboratory design is used primarily in facilities in which experiments of moderate to high potential hazard are performed.

Combinations of laboratory practices, containment equipment, and special laboratory design can be made to achieve different levels of physical containment. Four levels of physical containment, which are designated as P1, P2, P3, and P4, are described. It should be emphasized that the descriptions and assignments of physical containment detailed below are based on existing approaches to containment of pathogenic organisms. For example, the "Classification of Etiologic Agents on the Basis of Hazard," [7] prepared by the Center for Disease Control, describes four general levels which roughly correspond to our descriptions for P1, P2, P3, and P4; and the National Cancer Institute describes three levels for research on oncogenic viruses which roughly correspond to our P2, P3, and P4 levels. [8]

It is recognized that several different combinations of laboratory practices, containment equipment, and special laboratory design may be appropriate for containment of specific research activities. The Guidelines, therefore, allow alternative selections of primary containment equipment within facilities that have been designed to provide P3 and P4 levels of physical containment. The selection of alternative methods of primary containment is dependent, however, on the level of biological containment provided by the host-vector system used in the experiment. Consideration will also be given by the Director, NIH, with the advice of the Recombinant DNA Advisory Committee to other combinations which achieve an equivalent level of containment. (See Section IV-E-1-b-(2)-(b).) Additional material on physical containment for plant host-vector systems is found in Sections III-C-3 and III-C-4.

II-B-1. P1 Level.**II-B-1-a. Laboratory Practices.**

II-B-1-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-1-a-(2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-1-a-(3). All biological wastes shall be decontaminated before disposal. Other contaminated materials, such as glassware, animal cages, and laboratory equipment, shall be decontaminated before washing, reuse, or disposal.

II-B-1-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-1-a-(5). Eating, drinking, smoking, and storage of foods are not permitted in the laboratory area in which recombinant DNA materials are handled.

II-B-1-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-1-a-(7). Care shall be taken in the conduct of all procedures to minimize the creation of aerosols.

II-B-1-a-(8). Contaminated materials that are to be decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container, which is closed before removal from the laboratory.

II-B-1-a-(9). An insect and rodent control program shall be instituted.

II-B-1-a-(10). The use of laboratory gowns, coats, or uniforms is discretionary with the laboratory supervisor.

II-B-1-a-(11). Use of the hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-1-a-(12). The laboratory shall be kept neat and clean.

II-B-1-b. Containment Equipment. Special containment equipment is not required at the P1 level.

II-B-1-c. Special Laboratory Design. Special laboratory design is not required at the P1 level.

II-B-2. P2 Level.**II-B-2-a. Laboratory Practices.**

II-B-2-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-2-a-(2). Work surfaces shall be decontaminated daily, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-2-a-(3). All laboratory wastes shall be steam-sterilized (autoclaved) before disposal. Other contaminated materials such as glassware, animal cages, laboratory equipment, and radioactive wastes shall be decontaminated by a means demonstrated to be effective before washing, reuse, or disposal.

II-B-2-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-2-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory area in which recombinant DNA materials are handled.

II-B-2-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-2-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-2-a-(8). Contaminated materials that are to be steam sterilized (autoclaved) or decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container, which is closed before removal from the laboratory.

II-B-2-a-(9). Only persons who have been advised of the nature of the research being conducted shall enter the laboratory.

II-B-2-a-(10). The universal biohazard sign shall be posted on all laboratory access doors when experiments requiring P2 containment are in progress. Freezers and refrigerators or other units used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-2-a-(11). An insect and rodent control program shall be instituted.

II-B-2-a-(12). The use of laboratory gowns, coats, or uniforms is required. Laboratory clothing shall not be worn to the lunch room or outside of the building in which the laboratory is located.

II-B-2-a-(13). Animals not related to the experiment shall not be permitted in the laboratory.

II-B-2-a-(14). Use of the hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-2-a-(15). The laboratory shall be kept neat and clean.

II-B-2-a-(16). Experiments of lesser biohazard potential can be carried out concurrently in carefully demarcated areas of the same laboratory.

II-B-2-b. Containment Equipment. Biological safety cabinets[20] shall be used to contain aerosol-producing equipment, such as blenders, lyophilizers, sonicators, and centrifuges, when used to process organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol. For example, a centrifuge may

be operated in the open if a sealed head or safety centrifuge cups are used.

II-B-2-c. Special Laboratory Design. An autoclave for sterilization of wastes and contaminated materials shall be available in the same building in which organisms containing recombinant DNA molecules are used.

II-B-3. P3 Level.**II-B-3-a. Laboratory Practices.**

II-B-3-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-3-a-(2). Work surfaces shall be decontaminated following the completion of the experimental activity, and immediately following spills of organisms containing recombinant DNA molecules.

II-B-3-a-(3). All laboratory wastes shall be steam-sterilized (autoclaved) before disposal. Other contaminated materials, such as glassware, animal cages, laboratory equipment, and radioactive wastes, shall be decontaminated by a method demonstrated to be effective before washing, reuse, or disposal.

II-B-3-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-3-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the laboratory area in which recombinant DNA materials are handled.

II-B-3-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-3-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-3-a-(8). Contaminated materials that are to be steam-sterilized (autoclaved) or decontaminated at a site away from the laboratory shall be placed in a durable leak-proof container, which is closed before removal from the laboratory.

II-B-3-a-(9). Entry into the laboratory shall be through a controlled access area. Only persons who have been advised of the nature of the research being conducted shall enter the controlled access area. Only persons required on the basis of program or support needs shall be authorized to enter the laboratory. Such persons shall be advised of the nature of the research being conducted before entry, and shall comply with all required entry and exit procedures.

II-B-3-a-(10). Persons under 16 years of age shall not enter the laboratory.

II-B-3-a-(11). The universal biohazard sign shall be posted on the controlled access area door and on all laboratory doors when experiments requiring P3-level containment are in progress. Freezers and refrigerators or other units used to store organisms containing recombinant DNA molecules shall also be posted with the universal biohazard sign.

II-B-3-a-(12). An insect and rodent control program shall be instituted.

II-B-3-a-(13). Laboratory clothing that protects street clothing (e.g., long-sleeve solid-front or wrap-around gowns, no-button or slipover jackets) shall be worn in the laboratory. Front-button laboratory coats are unsuitable. Laboratory clothing shall not be worn outside the laboratory and shall be decontaminated before it is sent to the laundry.

II-B-3-a-(14). Raincoats, overcoats, topcoats, coats, hats, caps, and such street outer-wear shall not be kept in the laboratory.

II-B-3-a-(15). Gloves shall be worn when handling materials requiring P3 containment. They shall be removed aseptically immediately after the handling procedure and decontaminated.

II-B-3-a-(16). Animals and plants not related to the experiment shall not be permitted in the laboratory.

II-B-3-a-(17). Vacuum outlets shall be protected by filter and liquid disinfectant traps.

II-B-3-a-(18). Use of hypodermic needle and syringe shall be avoided when alternative methods are available.

II-B-3-a-(19). The laboratory shall be kept neat and clean.

II-B-3-a-(20). If experiments involving other organisms which require lower levels of containment are to be conducted in the same laboratory concurrently with experiments requiring P3-level physical containment, they shall be conducted in accordance with all P3-level laboratory practices.

II-B-3-b. Containment Equipment.

II-B-3-b-(1). Biological safety cabinets [20] shall be used for all equipment and manipulations that produce aerosols—e.g., pipetting, dilutions, transfer operations, plating, flaming, grinding, blending, drying, sonicating, shaking, centrifuging—where these procedures involve organisms containing recombinant DNA molecules, except where equipment design provides for containment of the potential aerosol.

II-B-3-b-(2). Laboratory animals held in a P3 area shall be housed in

partial-containment caging systems, such as Horsfall units [19A], open cages placed in ventilated enclosures, solid-wall and -bottom cages covered by filter bonnets, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet radiation lamps and reflectors. (Note: Conventional caging systems may be used, provided that all personnel wear appropriate personal protective devices. These shall include, at a minimum, wrap-around gowns, head covers, gloves, shoe covers, and respirators. All personnel shall shower on exit from areas where these devices are required.)

II-B-3-b-(3). *Alternative Selection of Containment Equipment.* Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified in Part III can be conducted in the P3 laboratory using containment equipment specified for the P2 level of physical containment. Experimental procedures involving a host-vector system that provides a one-step lower level of biological containment than that specified in Part III can be conducted in the P3 laboratory using containment equipment specified for the P4 level of physical containment. Alternative combinations of containment safeguards are shown in Table I.

TABLE I.—Combinations of Containment Safeguards

Classification of experiment according to Guidelines		Alternate combinations of physical and biological containment			
Physical containment	Biological* containment	Physical Containment			Biological containment
		Laboratory design specified for:	Laboratory practices specified for:	Containment equipment specified for:	
P3	HV3	P3	P3	P3	HV3
P3	HV3	P3	P3	P4	HV2
P3	HV2	P3	P3	P3	HV2
P3	HV2	P3	P3	P2	HV3
P3	HV2	P3	P3	P4	HV1
P3	HV1	P3	P3	P3	HV1
P3	HV1	P3	P3	P2	HV2

*See section II-D for description of biological containment.

II-B-3-c. Special Laboratory Design.

II-B-3-c-(1). The laboratory shall be separated by a controlled access area from areas that are open to unrestricted traffic flow. A controlled access area is an anteroom, a change room, an air lock or any other double-door arrangement that separates the laboratory from areas open to unrestricted traffic flow.

II-B-3-c-(2). The surfaces of walls, floors, and ceilings shall be readily cleanable. Penetrations through these surfaces shall be sealed or capable of being sealed to facilitate space decontamination.

II-B-3-c-(3). A foot-, elbow-, or automatically-operated handwashing facility shall be provided near each primary laboratory exit area.

II-B-3-c-(4). Windows in the laboratory shall be sealed.

II-B-3-c-(5). An autoclave for sterilization of wastes and contaminated materials shall be available in the same building (and preferably within the controlled laboratory area) in which organisms containing recombinant DNA molecules are used.

II-B-3-c-(6). The laboratory shall have a ventilation system that is capable of controlling air movement. The movement of air shall be from areas of lower contamination potential to areas of higher contamination potential (i.e., from the controlled access area to the laboratory area). If the ventilation system provides positive pressure supply air, the system shall operate in a manner that prevents the reversal of the direction of air movement or shall be equipped with an alarm that would be actuated in the event that reversal in the direction of air movement were to occur. The exhaust air from the

laboratory area shall not be recirculated to other areas of the building unless the exhaust air is filtered by HEPA filters or equivalent. The exhaust air from the laboratory area can be discharged to the outdoors without filtration or other means for effectively reducing an accidental aerosol burden provided that it can be dispersed clear of occupied buildings and air intakes.

II-B-3-c-(7). The treated exhaust-air from Class I and Class II biological safety cabinets [20] may be discharged either to the laboratory or to the outdoors. The treated exhaust-air from a class III cabinet shall be discharged directly to the outdoors. If the treated exhaust-air from these cabinets is to be discharged to the outdoors through a building exhaust air system, it shall be connected to this system so as to avoid any interference with the air

balance of the cabinet and the building ventilation system.

II-B-4. P4 Level.

II-B-4-a. Laboratory Practices.

II-B-4-a-(1). Laboratory doors shall be kept closed while experiments are in progress.

II-B-4-a-(2). Work surfaces shall be decontaminated following the completion of the experimental activity and immediately following spills of organisms containing recombinant DNA molecules.

II-B-4-a-(3). All laboratory wastes shall be steam-sterilized (autoclaved) before disposal. Other contaminated materials such as glassware, animal cages, laboratory equipment, and radioactive wastes shall be decontaminated by a method demonstrated to be effective before washing, reuse, or disposal.

II-B-4-a-(4). Mechanical pipetting devices shall be used; pipetting by mouth is prohibited.

II-B-4-a-(5). Eating, drinking, smoking, and storage of food are not permitted in the P4 facility.

II-B-4-a-(6). Persons shall wash their hands after handling organisms containing recombinant DNA molecules and when they leave the laboratory.

II-B-4-a-(7). Care shall be exercised to minimize the creation of aerosols. For example, manipulations such as inserting a hot inoculating loop or needle into a culture, flaming an inoculation loop or needle so that it splatters, and forceful ejection of fluids from pipettes or syringes shall be avoided.

II-B-4-a-(8). Biological materials to be removed from the P4 facility in a viable or intact state shall be transferred to a nonbreakable sealed container, which is then removed from the P4 facility through a pass-through disinfectant dunk tank or fumigation chamber.

II-B-4-a-(9). No materials, except for biological materials that are to remain in a viable or intact state, shall be removed from the P4 facility unless they have been steam-sterilized (autoclaved) or decontaminated by a means demonstrated to be effective as they pass out of the P4 facility. All wastes and other materials as well as equipment not damaged by high tempera-

ture or steam shall be steam sterilized in the double-door autoclave of the P4 facility. Other materials which may be damaged by temperature or steam shall be removed from the P4 facility through a pass-through fumigation chamber.

II-B-4-a-(10). Materials within the Class III cabinets shall be removed from the cabinet system only after being steam-sterilized in an attached double-door autoclave or after being contained in a nonbreakable sealed container, which is then passed through a disinfectant dunk tank or a fumigation chamber.

II-B-4-a-(11). Only persons whose entry into the P4 facility is required to meet program or support needs shall be authorized to enter. Before entering, such persons shall be advised of the nature of the research being conducted and shall be instructed as to the appropriate safeguards to ensure their safety. They shall comply with instructions and all other required procedures.

II-B-4-a-(12). Persons under 18 years of age shall not enter the P4 facility.

II-B-4-a-(13). Personnel shall enter into and exit from the P4 facility only through the clothing change and shower rooms. Personnel shall shower at each egress from the P4 facility. Air locks shall not be used for personnel entry or exit except for emergencies.

II-B-4-a-(14). Street clothing shall be removed in the outer side of the clothing-change area and kept there. Complete laboratory clothing, including undergarments, head cover, shoes, and either pants and shirts or jumpsuits, shall be used by all persons who enter the P4 facility. Upon exit, personnel shall store this clothing in lockers provided for this purpose or discard it into collection hampers before entering the shower area.

II-B-4-a-(15). The universal biohazard sign is required on the P4 facility access doors and on all interior doors to individual laboratory rooms where experiments are conducted. The sign shall also be posted on freezers, refrigerators, or other units used to store organisms containing recombinant DNA molecules.

II-B-4-a-(16). An insect and rodent control program shall be instituted.

II-B-4-a-(17). Animals and plants not related to the experiment shall not be permitted in the laboratory in which the experiment is being conducted.

II-B-4-a-(18). Vacuum outlets shall be protected by filter and liquid disinfectant traps.

II-B-4-a-(19). Use of the hypodermic needle and syringe shall be avoided when alternate methods are available.

II-B-4-a-(20). The laboratory shall be kept neat and clean.

II-B-4-a-(21). If experiments involving other organisms which require lower levels of containment are to be conducted in the P4 facility concurrently with experiments requiring P4-level containment, they shall be conducted in accordance with all P4-level laboratory practices specified in this section.

II-B-4-b. Containment Equipment.

II-B-4-b-(1). Experimental procedures involving organisms that require P4-level physical containment shall be conducted either in (i) a Class III cabinet system or in (ii) Class I or Class II cabinets that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure isolation suits.

II-B-4-b-(2). Laboratory animals involved in experiments requiring P4-level physical containment shall be housed either in cages contained in Class III cabinets or in partial-containment caging systems (such as Horsfall units [19A], open cages placed in ventilated enclosures, or solid-wall and -bottom cages covered by filter bonnets, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors) that are located in a specially designed area in which all personnel are required to wear one-piece positive-pressure suits.

II-B-4-b-(3). *Alternative Selection of Containment Equipment.* Experimental procedures involving a host-vector system that provides a one-step higher level of biological containment than that specified in Part III can be conducted in the P4 facility using containment equipment requirements specified for the P3 level of physical containment. Alternative combinations of containment safeguards are shown in Table II.

TABLE II.—Combinations of Containment Safeguards

Classification of experiment according to Guidelines		Alternate combinations of physical and biological containment			
Physical containment	Biological * containment	Physical containment			
		Laboratory design specified for:	Laboratory practices specified for:	Containment equipment specified for:	Biological containment
P4 P4	HV1 HV1	P4 P4	P4 P4 **	P4 P3	HV1 HV2

* See Section II-D for description of biological containment. ** In this case gloves shall be worn, in addition to the clothing requirements specified in II-B-4-a-(14).

II-B-4-c. *Special Laboratory Design.*

II-B-4-c-(1). The laboratory shall be located in a restricted-access facility which is either a separate building or a clearly demarcated and isolated zone within a building. Clothing-change areas and shower rooms shall be provided for personnel entry and egress. These rooms shall be arranged so that personnel leave through the shower area to the change room. A double-door ventilated vestibule or ultraviolet air lock shall be provided for passage of materials, supplies, and equipment which are not brought into the P4 facility through the change room area.

II-B-4-c-(2). Walls, floors, and ceilings of the P4 facility are constructed to form an internal shell which readily allows vapor-phase decontamination and is animal- and insect-proof. All penetrations through these structures and surfaces are sealed. (The integrity of the walls, floors, ceilings, and penetration seals should ensure adequate containment of a vapor-phase decontaminant under static pressure conditions. This requirement does not imply that these surfaces must be airtight.)

II-B-4-c-(3). A foot-, elbow-, or automatically-operated handwashing facility shall be provided near the door within each laboratory in which experiments involving recombinant DNA are conducted in openface biological safety cabinets.

II-B-4-c-(4). Central vacuum systems are permitted. The system, if provided, shall not serve areas outside the P4 facility. The vacuum system shall include in-line HEPA filters near each use point or service cock. The filters shall be installed so as to permit in-place decontamination and replacement. Water supply and liquid and gaseous services provided to the P4 facility shall be protected by devices that prevent backflow.

II-B-4-c-(5). Drinking water fountains shall not be installed in laboratory or animal rooms of the P4 facility. Foot-operated water fountains are permitted in the corridors of the P4 facility. The water service provided to such fountains shall be protected from the water services to the laboratory areas of the P4 facility.

II-B-4-c-(6). Laboratory doors shall be self-closing.

II-B-4-c-(7). A double-door autoclave shall be provided for sterilization of material passing out of the P4 facility. The autoclave doors shall be interlocked so that both doors will not be open at the same time.

II-B-4-c-(8). A pass-through dunk tank or fumigation chamber shall be provided for removal from the P4 facility of material and equipment that cannot be heat-sterilized.

II-B-4-c-(9). All liquid effluents from the P4 facility shall be collected and decontaminated before disposal.

Liquid effluents from biological safety cabinets and laboratory sinks shall be sterilized by heat. Liquid effluents from the shower and hand washing facilities may be inactivated by chemical treatment. HEPA filters shall be installed in all vents from effluent drains.

II-B-4-c-(10). An individual supply and exhaust-air ventilation system shall be provided. The system shall maintain pressure differentials and directional air flow as required to ensure inflow from areas outside the facility toward areas of highest potential risk within the facility. The system shall be designed to prevent the reversal of air flow. The system shall sound an alarm in the event of system malfunction.

II-B-4-c-(11). Air within individual laboratories of the P4 facility may be recirculated if HEPA filtered.

II-B-4-c-(12). The exhaust air from the P4 facility shall be HEPA filtered and discharged to the outdoors so that it is dispersed clear of occupied buildings and air intakes. The filter chambers shall be designed to allow *in situ* decontamination before removal and to facilitate certification testing after replacement.

II-B-4-c-(13). The treated exhaust-air from Class I and Class II biological safety cabinets [20] may be discharged directly to the laboratory room environment or to the outdoors. The treated exhaust-air from Class III cabinets shall be discharged to the outdoors. If the treated exhaust-air from these cabinets is to be discharged to the outdoors through the P4 facility exhaust air system, it shall be connected to this system so as to avoid any interference with the air balance of the cabinets or the facility exhaust air system.

II-B-4-b-(14). As noted in Section II-B-4-c-(1), the P4 facility may contain specially designed areas in which all personnel are required to wear one-piece positive-pressure isolation suits. Such areas shall be airtight. The exhaust-air from the suit area shall be filtered by two sets of HEPA filters installed in series, and a duplicate filtration unit and exhaust fan shall be provided. The air pressure within the suit area shall be less than that in any adjacent area. An emergency lighting system, communication systems, and power source shall be provided. A double-door autoclave shall be provided for sterilization of all waste materials to be removed from the suit area.

Personnel who enter this area shall wear a one-piece positive-pressure suit that is ventilated by a life-support system. The life-support system shall be provided with alarms and emergency backup air. Entry to this area is through an airlock fitted with airtight doors. A chemical shower area shall be

provided to decontaminate the surfaces of the suit before removal.

II-C. *Shipment.* Recombinant DNA molecules contained in an organism or virus shall be shipped only as an etiologic agent under requirements of the U.S. Public Health Service and the U.S. Department of Transportation (§ 72.25, Part 72, Title 42, and §§ 173.386-388, Part 173, Title 49, U.S. Code of Federal Regulations) as specified below:

II-C-1. Recombinant DNA molecules contained in an organism or virus requiring P1, P2, or P3 physical containment, when offered for transportation or transported, are subject to all requirements of § 72.25(c)(1)-(5), Part 72, Title 42 CFR, and §§ 173.386-388, Part 173, Title 49 CFR.

II-C-2. Recombinant DNA molecules contained in an organism or virus requiring P4 physical containment, when offered for transportation or transported, are subject to the requirements listed above under II-C-1 and are also subject to § 72.25(c)(6), Part 72, Title 42 CFR.

II-C-3. Additional information on packaging and shipment is given in the "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research."

II-D. *Biological Containment.*

II-D-1. *Levels of Biological Containment.* In consideration of biological containment, the vector (Plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered together. Any combination of vector and host which is to provide biological containment must be chosen or constructed so that the following types of "escape" are minimized: (i) Survival of the vector in its host outside the laboratory and (ii) transmission of the vector from the propagation host to other nonlaboratory hosts.

The following levels of biological containment (HV, or Host-Vector, systems) for prokaryotes will be established; specific criteria will depend on the organisms to be used. Eukaryotic host-vector systems are considered in Part III.

II-D-1-a. *HV1.* A host-vector system which provides a moderate level of containment. *Specific systems:*

II-D-1-a-(1). *EK1.* The host is always *E. Coli* K-12 or a derivative thereof, and the vectors include non-conjugative plasmids (e.g., pSC101, ColE1, or derivatives thereof [21-27]) and variants of bacteriophage, such as [28-33]. The *E. Coli* K-12 hosts shall not contain conjugation-proficient plasmids, whether autonomous or integrated, or generalized transducing phages.

II-D-1-a-(2). Other Prokaryotes. Hosts and vectors shall be, at a minimum, comparable in containment to *E. Coli* K-12 with a non conjugative plasmid or bacteriophage vector. The data to be considered and mechanism for approval of such HV1 systems are described below (Section II-D-2).

II-D-1-b. HV2 These are host-vector systems shown to provide a high level of biological containment as demonstrated by data from suitable tests performed in the laboratory. Escape of the recombinant DNA either via survival of the organisms or via transmission of recombinant DNA to other organisms should be less than 10^{-6} under specified conditions. *Specific systems:*

II-D-1-b-(1). For EK2 host-vector systems in which the vector is a plasmid, no more than one in 10^8 host cells should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment, either by survival of the original host or as a consequence of transmission of the cloned DNA fragment.

II-D-1-b-(2). For EK2 host-vector systems in which the vector is a phage, no more than one in 10^8 phage particles should be able to perpetuate a cloned DNA fragment under the specified nonpermissive laboratory conditions designed to represent the natural environment either (i) as a prophage (in the inserted or plasmid form) in the laboratory host used for phage propagation or (ii) by surviving in natural environments and transferring a cloned DNA fragment to other hosts (or their resident prophages).

II-D-1-c. HV3. These are host-vector systems in which:

II-D-1-c-(1). All HV2 criteria are met.

II-D-1-c-(2). The vector is dependent on its propagation host or is highly defective in mobilizability. Reversion to host-independence must be less than 10^{-6} per vector genome per generation.

II-D-1-c-(3). No markers conferring resistance to antibiotics commonly used clinically or in agriculture are carried by the vector, unless expression of such markers is dependent on the propagating host or on unique laboratory-controlled conditions or is blocked by the inserted DNA.

II-D-1-c-(4). The specified containment shown by laboratory tests has been independently confirmed by specified tests in animals, including primates, and in other relevant environments.

II-D-1-c-(5). The relevant genotypic and phenotypic traits have been independently confirmed.

II-D-2. Certification of Host-Vector Systems.

II-D-2-a. Responsibility. HV1 systems other than *E. coli* K-12, and HV2 and HV3 host-vector systems, may not be designated as such until they have been certified by the Director, NIH. Application for certification of a host-vector system is made by written application to the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20014.

Host-vector systems that are proposed for certification will be reviewed by the NIH Recombinant DNA Advisory Committee (RAC). (See Section IV-E-1-b-(1)-(c).) This will first involve review of the data on construction, properties, and testing of the proposed host-vector system by a Working Group composed of one or more members of the RAC and other persons chosen because of their expertise in evaluating such data. The Committee will then evaluate the report of the Working Group and any other available information at a regular meeting. The Director, NIH is responsible for certification after receiving the advice of the RAC. Minor modifications of existing certified host-vector systems, where the modifications are of minimal or no consequence to the properties relevant to containment may be certified by the Director, NIH without review by the RAC. (See Section IV-E-1-b-(3)-(h).)

When new host-vector systems are certified, notice of the certification will be sent by ORDA to the applicant and to all IBCs and will be published in the *Recombinant DNA Technical Bulletin*. Copies of a list of all currently certified host-vector systems may be obtained from ORDA at any time.

The Director, NIH may at any time rescind the certification of any host-vector system. (See Section IV-E-1-b-(3)-(i).) If certification of a host-vector system is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system, or use the clones at a higher physical containment level unless NIH determines that the already constructed clones incorporate adequate biological containment.

Certification of a given system does not extend to modifications of either the host or vector component of that system. Such modified systems must be independently certified by the Director, NIH. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications of a certified system require the submission of complete testing data.

II-D-2-b. Data To Be Submitted for Certification.

II-D-2-b-(1). HV1 Systems Other than *E. Coli* K-12. The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction and survival and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and what sort of information is exchanged; and any relevant information on its pathogenicity or toxicity. (ii) A description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information. (iii) A general description of the range of experiments contemplated, with emphasis on the need for developing such an HV1 system.

II-D-2-b-(2). HV2 Systems. Investigators planning to request HV2 certification for host-vector systems can obtain instructions from ORDA concerning data to be submitted [33A, 33B]. In general, the following types of data are required: (i) Description of construction steps, with indication of source, properties, and manner of introduction of genetic traits. (ii) Quantitative data on the stability of genetic traits that contribute to the containment of the system. (iii) Data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment. (iv) Data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and nonpermissive conditions. (v) Data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation. (vi) In some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals (e.g., rodents). Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments.

Data must be submitted in writing to ORDA. Ten to twelve weeks are normally required for review and circulation of the data prior to the meeting at which such data can be considered by the NIH Recombinant DNA Advisory Committee (RAC). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed HV2 systems prior to consideration of the system by the RAC and its subcommittee. More spe-

cific instructions concerning the type of data to be submitted to NIH for proposed EK2 systems involving either plasmids or bacteriophage ϕ in *E. coli* K-12 are available from ORDA.

II-D-2-b-(3). *HV3 Systems*. Putative HV3 systems must, as the first step in certification, be certified as HV2 systems. Systems which meet the criteria given above under II-D-1-(c)-1, II-D-1-(c)-2, II-D-1-(c)-3 will then be recommended for HV3 testing. Tests to evaluate various HV2 host-vector systems for HV3 certification will be performed by contractors selected by NIH. These contractors will repeat tests performed by individuals proposing the HV2 system and, in addition, will conduct more extensive tests on conditions likely to be encountered in nature. The genotypic and phenotypic traits of HV2 systems will be evaluated. Tests on survival and transmissibility in and on animals, including primates, will be performed, as well as tests on survival in certain specified natural environments.

II-D-3. *Distribution of Certified Host-Vectors*. Certified HV2 and HV3 host-vector systems (plus appropriate control strains) must be obtained from the NIH or its designees, one of whom will be the investigator who developed the system. NIH shall announce the availability of the system by publication of notices in appropriate journals.

Plasmid vectors will be provided in a suitable host strain, and phage vectors will be distributed as small-volume lysates. If NIH propagates any of the host strains or phage, a sample will be sent to the investigator who developed the system or to an appropriate contractor, prior to distribution, for verification that the material is free from contamination and unchanged in phenotypic properties.

In distributing the certified HV2 and HV3 host-vector systems, NIH or its designee will (i) send out a complete description of the system; (ii) enumerate and describe the tests to be performed by the user in order to verify important phenotypic traits; (iii) remind the user that any modification of the system necessitates independent approval of the system by the NIH; and (iv) remind the user of responsibility for notifying ORDA of any discrepancies with the reported properties or any problems in the safe use of the system.

NIH may also distribute certified HV1 host-vector systems.

III. CONTAINMENT GUIDELINES FOR COVERED EXPERIMENTS

Part III discusses experiments covered by the Guidelines. The reader must first consult Part I, where listings are given of prohibited and exempt experiments.

Containment guidelines for permissible experiments are given in Part III. Changes in these levels for specific experiments (or the assignment of levels to experiments not explicitly considered here) may not be instituted without the express approval of the Director, NIH. (See Sections IV-E-1-b-(1)-(a), IV-E-1-b-(1)-(b), IV-E-1-b-(2)-(b), IV-E-1-b-(2)-(c), and IV-E-1-b-(3)-(b).)

III-A. *Classification of Experiments Using the E. coli K-12 Host-Vector Systems*. Most recombinant DNA experiments currently being done employ *E. coli* K-12 host-vector systems. These are the systems for which we have the most experience and knowledge (i) regarding the effectiveness of biological containment provided by existing hosts and vectors and (ii) necessary for the construction of more effective biological barriers. We therefore consider DNA recombinants in *E. coli* K-12 before proceeding to other host-vector systems. The levels of biological containment for *E. coli* K-12 systems are designated EK1, EK2, and EK3 in ascending order.

It has been necessary, throughout this section, to use words and such terms are marked with footnote reference numbers. These footnotes (Part V) define more fully what the terms denote.

In the following classification of containment criteria for different kinds of recombinant DNAs, the stated levels of physical and biological containment are minimal for the experiments designated. The use of higher levels of biological containment (EK3 > EK2 > EK1) is encouraged if they are available and equally appropriate for the purposes of the experiment.

III-A-1. *Shotgun Experiments*. These experiments involve the production of recombinant DNAs between the vector and portions of the specified cellular source, preferably a partially purified fraction. Care should be taken either to preclude or eliminate contaminating microorganisms before isolating the DNA.

III-A-1-a. *Eukaryotic DNA Recombinants*.

III-A-1-a-(1). *Primates*. P2 physical containment + an EK2 host-vector. Any lowering of containment below these levels (i.e., for purified DNA or characterized clones) cannot be made solely by an institutional biosafety committee but requires NIH approval. (See Section IV-E-1-b-(3)-(e).)

III-A-1-a-(2). *Other Mammals*. P2 physical containment + an EK2 host-vector.

III-A-1-a0(3). *Birds*. P2 physical containment + an EK2 host-vector, or P3 + EK1.

III-A-1-a-(4). *Cold-Blooded Vertebrates*. P2 physical containment + an EK1 host-vector or P1 + EK2. If the

eukaryote is known to produce a potent polypeptide toxin, [34] the containment shall be increased to P3 + EK2.

III-A-1-a-(5). *Other Cold-Blooded Animals and Lower Eukaryotes*. This large class of eukaryotes is divided into two groups:

III-A-1-a-(5)-(a). Species that are known to produce a potent polypeptide toxin [34] that acts in vertebrates, or are known pathogens listed in Class 2, [1] or are known to carry such pathogens must use P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked eukaryote genes, containment may be reduced to P3 + EK1 or P2 + EK2. Species that produce potent toxins that affect invertebrates or plants but not vertebrates require P2 + EK2 or P3 + EK1. Any species that has a demonstrated capacity for carrying particular pathogenic microorganisms is included in this group, unless the organisms used as the source of DNA have been shown not to contain those agents, in which case they may be placed in the following group. [2A]

III-A-1-a-(5)-(b). The remainder of the species in this class including plant pathogenic or symbiotic fungi that do not produce potent toxins: P2 + EK1 or P1 + EK2. However, any insect in this group must be either (i) grown under laboratory conditions for at least 10 generations prior to its use as a source of DNA, or (ii) if caught in the wild, must be shown to be free of disease-causing microorganisms or must belong to a species that does not carry microorganisms causing disease in vertebrates or plants. [2A] If these conditions cannot be met, experiments must be done under P3 + EK1 or P2 + EK2 containment.

III-A-1-a-(6). *Plants*. P2 physical containment + an EK1 host-vector, or P1 + EK2. If the plant source makes a potent polypeptide toxin, [34] the containment must be raised to P3 physical containment + an EK2 host-vector. When the potent toxin is not a polypeptide and is likely not to be the product of closely linked plant genes, containment may be reduced to P3 + EK1 or P2 + EK2. [2A]

III-A-1-b. *Prokaryotic DNA Recombinants*.

III-A-1-b-(1). *Prokaryotes That Exchange Genetic Information* [35] with *E. coli*. Those prokaryotes that exchange genetic information with *E. coli* by known physiological processes will be exempted from these Guidelines if they appear on the "list of exchangers" set forth in Appendix A (see Section I-E-4).

For those not on the list, the containment levels are P1 physical containment + an EK1 host-vector. In

fact, experiments in this category may be performed with any *E. coli* K-12 vector (e.g., conjugative plasmids). However, for prokaryotes that are classified [1] as Class 2, the containment levels are P2 + EK1.

III-A-1-b-(2). *Prokaryotes That Do Not Exchange Genetic Information with E. Coli*. P2 physical containment + an EK1 host-vector, or P1 + EK2, except for DNA from Class 2 agents, [1] which require P3 + EK2.

III-A-2. *Plasmids, Bacteriophages, and Other Viruses*. Recombinants formed between a vector and some other plasmid or virus DNA have in common the potential for acting as double vectors because of the replication functions in these DNAs. The containment conditions given below apply only to propagation of the DNA recombinants in *E. coli* K-12 hosts. They do not apply to other hosts in which the recombinants may be able to replicate as a result of functions provided by the DNA inserted into the EK vectors. These are considered under other host-vector systems.

III-A-2-a. *Viruses of Eukaryotes* (summary given in Table III).

III-A-2-a-(1). *DNA Viruses*.

III-A-2-a-(1)-(a). *Nontransforming viruses*.

III-A-2-a-(1)-(a)-(1). *Adeno-Associated Viruses, Minute Virus of Mice, Mouse Adenovirus (Strain FL), and Plant Viruses*. P1 physical containment + and EK1 host-vector shall be used for DNA recombinants produced with (i) the whole viral genome, (ii) subgenomic DNA segments, or (iii) purified cDNA copies of viral mRNA. [37]

III-A-2-a-(1)-(a)-(2). *Hepatitis B*.

III-A-2-a-(1)-(a)-(2)-(a). P1 physical containment + an EK1 host-vector shall be used for purified subgenomic DNA segments. [38]

III-A-2-a-(1)-(a)-(2)-(b). P2 physical containment + an EK2 host-vector, or P3 + EK1, shall be used for DNA for recombinants produced with the whole viral genome or with subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(1)-(a)-(2)-(c). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for DNA recombinants derived from purified cDNA copies of viral mRNA. [37]

III-A-2-a-(1)-(a)-(3). *Other Nontransforming Members of Presently Classified Viral Families*. [36]

III-A-2-a-(1)-(a)-(3)-(a). P1 physical containment + an EK1 host-vector shall be used for (i) DNA recombinants produced with purified subgenomic DNA [38] segments or (ii) purified cDNA copies of viral mRNA. [37]

III-A-2-a-(1)-(a)-(3)-(b). P1 physical containment + an EK1 host and a vector certified for use in an EK2 system shall be used for DNA recombinants produced with the whole viral genome or with subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(1)-(b). *Transforming Viruses*. [37A]

III-A-2-a-(1)-(b)-(1). *Herpes Simplex, Herpes Ateles, and Epstein Barr Virus*. [39]

III-A-2-a-(1)-(b)-(1)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments. [38]

III-A-2-a-(1)-(b)-(1)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for (i) DNA recombinants produced with purified subgenomic DNA segments containing an entire transforming gene [38] or (ii) purified cDNA copies of viral mRNA. [37]

III-A-2-a-(1)-(b)-(1)-(c). P3 physical containment + an EK1 host-vector, or P2 + EK2, shall be used for DNA recombinants produced with the whole viral genome or with subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(1)-(b)-(2). *Other Transforming Members of Presently Classified Viral Families*. [36]

III-A-2-a-(1)-(b)-(2)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments. [38]

III-A-2-a-(1)-(b)-(2)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for (i) DNA recombinants produced with the whole viral genome, (ii) subgenomic DNA segments containing an entire transforming gene, (iii) purified cDNA copies of viral mRNA, [37] or (iv) subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(2). *DNA Transcripts of RNA Viruses*.

III-A-2-a-(2)-(a). *Retroviruses*.

III-A-2-a-(2)-(a)-(1). *Gibbon Ape,*

Woolly Monkey, Feline Leukemia and Feline Sarcoma Viruses. [39]

III-A-2-a-(2)-(a)-(1)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments. [38]

III-A-2-a-(2)-(a)-(1)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for DNA recombinants produced with purified subgenomic DNA segments [38] containing an entire transforming gene.

III-A-2-a-(2)-(a)-(1)-(c). P2 physical containment + an EK2 host-vector, or P3 + EK1, shall be used for DNA recombinants produced with (i) the whole viral genome, (ii) purified cDNA copies of viral mRNA, [37] or (iii) subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(2)-(a)-(2). *Other Members of the Family Retroviridae*. [36]

III-A-2-a-(2)-(a)-(2)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified nontransforming subgenomic DNA segments. [38]

III-A-2-a-(2)-(a)-(2)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for DNA recombinants produced with (i) subgenomic DNA segments containing an entire transforming gene, (ii) the whole viral genome, or (iii) purified cDNA copies of viral mRNA, [37] or (iv) subgenomic segments that have not been purified to the extent required in footnote 38.

III-A-2-a-(2)-(b). *Negative Strand RNA Viruses*. P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA. [37]

III-A-2-a-(2)-(c). *Plus-Strand RNA Viruses*.

III-A-2-a-(2)-(c)-(1). *Types 1 and 2 Sabin Poliovirus Vaccine Strains and Strain 17D (Theiler) of Yellow Fever Virus*. P1 physical containment + and EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole viral genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA. [37]

III-A-2-a-(2)-(c)-(2). *Other Plus-Strand RNA Viruses Belonging to Presently Classified Viral Families*. [36]

Recommended Containment for Cloning of Viral DNA or cDNA in *E. coli* K-12 Host-Vector Systems
(See text for full details)

Virus class	Type of viral DNA segment to be cloned				cDNA from viral mRNA [37]
	Subgenomic [38]		Genomic		
	Nontransforming segment	Segment containing an entire transforming gene	Nonsegmented genome	Segmented genome	
<u>DNA</u>					
Nontransforming viruses					
AAV, WM, Mouse Adeno (Strain FL)	P1 + EK1		P1 + EK1		P1 + EK1
Plant Viruses	P1 + EK1		P1 + EK1		P1 + EK1
Hepatitis B	P1 + EK1 [38]		P2 + EK2 or P3 + EK1		P2 + EK1CV [40] or P3 + EK1
Other	P1 + EK1 [38]		P1 + EK1CV [40]		P1 + EK1
Transforming Viruses					
Herpes Saimiri, H. Ateles and EBV [39]	P1 + EK1 [38]	P2 + EK1CV [40] or P3 + EK1 [38]	P2 + EK2 or P3 + EK1		P2 + EK1CV [40] or P3 + EK1
Other	P1 + EK1 [38]	P2 + EK1CV [40] or P3 + EK1	P2 + EK1CV [40] or P3 + EK1		P2 + EK1CV [40] or P3 + EK1
<u>RNA</u>					
Retroviruses					
Gibbon Ape, Woolly Monkey FeLV and FeSV [39]	P1 + EK1 [38]	P2 + EK1CV [40] or P3 + EK1 [38]	P2 + EK2 or P3 + EK1		P2 + EK2 or P3 + EK1
Other	P1 + EK1 [38]	P2 + EK1CV [40] or P3 + EK1	P2 + EK1CV [40] or P3 + EK1		P2 + EK1CV [40] or P3 + EK1

Table III

Recommended Containment for Cloning of Viral DNA or cDNA in *E. coli* K-12 Host-Vector Systems
(See text for full details)

Virus class	Type of viral DNA segment to be cloned				cDNA from viral mRNA[37]
	Subgenomic[38]		Genomic		
	Nontransforming segment	Segment containing an entire transforming gene	Nonsegmented genome	Segmented genome	
Negative-Strand RNA	P1 + EK1		P1 + EK1	P1 + EK1	P1 + EK1
Plus-Strand RNA					
Types 1 and 2 Sabin Polio, 17D	P1 + EK1		P1 + EK1		P1 + EK1
Yellow Fever Vaccine Strains	P1 + EK1[38]		P2 + EK1CV[40] or P3 + EK1		P2 + EK1CV[40] or P3 + EK1
Other					
Double-Stranded RNA	P1 + EK1			P1 + EK1	P1 + EK1
Plant Viruses + Viroids	P1 + EK1		P1 + EK1	P1 + EK1	P1 + EK1
Intracellular Viral DNA	See text	See text	See text		

II-A-2-a-(2)-(c)-(2)-(a). P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with purified subgenomic cDNA segments.[38]

III-A-2-a-(2)-(c)-(2)-(b). P2 physical containment + an EK1 host and a vector certified for use in an EK2 system, or P3 + EK1, shall be used for DNA recombinants produced with (i) cDNA copies of the whole genome, or (ii) purified cDNA copies of viral mRNA.[37]

III-A-2-a-(2)-(d). *Double-Stranded Segmented RNA Viruses*. P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) mixtures of subgenomic cDNA segments, (ii) a specific subgenomic cDNA segment, or (iii) purified cDNA copies of viral mRNA.[37]

III-A-2-a-(2)-(e). *RNA Plant Viruses and Plant Viroids*. P1 physical containment + an EK1 host-vector shall be used for DNA recombinants produced with (i) cDNA copies of the whole viral genome, (ii) subgenomic cDNA segments, or (iii) purified cDNA copies of viral mRNA.[37]

III-A-2-a-(3). *Intracellular Viral DNA*. Physical and biological containment specified for shotgun experiments with eukaryotic cellular DNA [see Section III-A-(1)-(a)] shall be used for DNA recombinants produced with integrated viral DNA or viral genomes present in infected cells.

III-A-2-b. *Eukaryotic Organelle DNAs*. P2 physical containment + an EK1 host-vector, or P1 + EK2, for mitochondrial or chloroplast DNA from eukaryotes when the organelle DNA has been obtained from isolated organelles. Otherwise, the conditions given for shotgun experiments apply.

III-A-2-c. *Prokaryotic Plasmid and Phage DNAs*. The containment levels required for shotgun experiments with DNA from prokaryotes apply to their plasmids or phages.

III-A-3. *Lowering of Containment Levels for characterized or Purified DNA Preparations and Clones*. Many of the risks which might conceivably arise from some types of recombinant DNA experiments, particularly shotgun experiments, would result from the inadvertent cloning of a harmful sequence. Therefore, in case where the risk of inadvertently cloning the "wrong" DNA is reduced by prior enrichment for the desired piece, or in which a clone made from a random assortment of DNAs has been purified and the absence of harmful sequences established, the containment conditions for further work may be reduced. The following section outlines the mechanisms for such reductions.

III-A-3-a. *Purified DNA Other than Plasmids, Bacteriophages, and Other Viruses*. The formation of DNA recombinants from cellular DNAs that have

been purified [41] and in which the absence of harmful sequences had been established [3] can be carried out under lower containment conditions than used for the corresponding shotgun experiment.[42] The containment may be decreased one step in physical containment (P4 → P3; P3 → P2; P2 → P1) while maintaining the biological containment specified for the shotgun experiment, or one step in biological containment (EK3 → EK2; EK2 → EK1) while maintaining the specified physical containment. The institutional biosafety committee (IBC) must review such a reduction and the approval of the IBC must be secured before such a reduction may be put into effect. (See Section IV-D-3-b.) The IBC must notify the NIH Office of Recombinant DNA activities (ORDA) in writing of all such approvals within 30 days after they take place. IBC approval is sufficient for such a reduction except for (i) primate DNA, which also requires prior NIH approval (see Section III-A-1-a-(1)), or (ii) any lowering of containment under Section III-A-3-a to levels below P1 + EK1, which also requires prior NIH approval. (See Sections IV-D-1-c, IV-E-1-b-(3)-(e), and IV-E-1-b-(3)-(f).)

III-A-3-b. *Characterized Clones of DNA Recombinants*. When a cloned DNA recombinant has been rigorously characterized and the absence of harmful sequences has been established (3), experiments involving this recombinant DNA may be carried out under lower containment conditions, as described below.

III-A-3-b-(1). Institutional biosafety committees (IBCs) may give approval for a single-step reduction in physical or biological containment on receipt of evidence of characterization of a clone derived from a shotgun experiment and its probable freedom from harmful genes. (See Section IV-D-3-b.) The IBC must notify ORDA in writing of all such approvals within 30 days after they take place. IBC approval is sufficient for such a reduction except for (i) primate DNA, which requires prior NIH approval (see Section III-A-1-a-(1)), or (ii) any lowering of containment under Section III-A-3-b to levels below P1 + EK1, which also requires prior NIH approval. (See Sections IV-D-1-c, IV-E-1-b-(3)-(e) and IV-E-1-b-(3)-(f).)

III-A-3-b-(2). Reduction of containment levels by more than one step, or cases involving primate DNA, or cases involving lowering of containment under Section III-A-3-b to levels below P1 + EK1, will require prior approval by NIH. (See Sections IV-E-1-b-(3)-(e), -(f) and -(g).)

III-B. *Experiments with Other Prokaryotic Host-Vectors*.

III-B-1. *HV1 Systems*. Host-vector systems which have been approved as

HV1 systems may be used under P2 containment conditions for shotgun experiments with phages, plasmids, and DNA from nonpathogenic prokaryotes which do not produce polypeptide toxins.[34]

Other classes of recombinant DNA experiments with these HV1 systems will require prior approval and classification by NIH. Experiments with DNAs from eukaryotes (and their plasmids or viruses) will generally follow the criteria for the corresponding experiments with *E. coli* K-12 host-vectors if the major habitats of the given host-vector overlap those of *E. coli*. The habitats of other host-vector systems should also be considered in relation to containment.

II-B-2. *Return of DNA Segments to Non-HV1 Host of Origin*. Those prokaryotes that exchange genetic information with *E. coli* by known physiological processes will be exempt from these Guidelines if they appear on the "list of exchangers" set forth in Appendix A (see Section I-E-4). For a prokaryote which can exchange genetic information [35] with *E. coli* under laboratory conditions but which is not on the list (Host A), the following type of experiment may be carried out under P-1 conditions without Host A having been approved as an HV1 host: DNA from Host A may be inserted into a vector and propagated in *E. coli* K-12 under P-1 conditions. Subsequently, this recombinant DNA may be returned to Host A by mobilization, transformation, or transduction and may then be propagated in Host A in any desired vector under P1 conditions.

For a prokaryote which does not exchange genetic information with *E. coli* (Host B), the following type of experiment may be carried out without Host B having been approved as an HV1 host: DNA from Host B may be inserted into a vector from a certified EK2 host-vector system and propagated in *E. coli* K-12 under the appropriate containment conditions [see Section III-A-1-b-(2)]. Subsequently, this recombinant DNA may be returned to Host B and propagated in Host B under P1 conditions.[43]

III-B-3. *Non-HV1 Systems*. Containment levels for other classes of experiments involving non-HV1 systems may be approved by the Director, NIH. (See Sections IV-E-1-b-(1)-(b), IV-E-1-b-(2)-(c) and IV-E-1-b-(3)-(b).)

III-C. *Experiments with Eukaryotic Host-Vectors*.

III-C-1. *Vertebrate Host-Vector Systems*. [44] (Summary given in Table IV).

III-C-1-a. *Polyoma Virus*.

III-C-1-a-(1). *Productive Virus-Cell Interactions*.

III-C-1-a-(1)-(a). Defective or whole polyoma virus genomes, with appropri-

ate helper, if necessary, can be used in P2 conditions to propagate DNA sequences:

III-C-1-a-(1)-(a)-(1). from bacteria of class 1 or class 2[1] or their phages or plasmids, except for those that produce potent polypeptide toxins; [34]

III-C-1-a-(1)-(a)-(2). from mice;

III-C-1-a-(1)-(a)-(3). from eukaryotic organisms that do not produce potent polypeptide toxins, [34] provided that the DNA segment is > 99% pure.

III-C-1-a-(1)-(b). Defective polyoma genomes, with appropriate helper, if necessary, can be used in P2 conditions for shotgun experiments to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins. [34]

III-C-1-a-(1)-(c). Whole virus genomes with appropriate helper, if necessary, can be used in P3 conditions for shotgun experiments to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins. [34]

III-C-1-a-(1)-(d). Experiments involving the use of defective polyoma virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis [45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-a-(2). *Nonproductive Virus-Cell Interactions*. Defective or whole polyoma virus genomes can be used as vectors in P2 conditions when production of viral particles cannot occur (e.g., transformation of nonpermissive cells or propagation of an unconditionally defective recombinant genome in the absence of helper), provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis [45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-b. *Simian Virus 40*.

III-C-1-b-(1). *Productive Virus-Cell Interactions*.

III-C-1-b-(1)-(a). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from:

III-C-1-b-(1)-(a)-(1). bacteria of Class 1 or Class 2, -1] or their phages or plasmids, except for those that produce potent polypeptide toxins; [34]

III-C-1-b-(1)-(a)-(2). uninfected African green monkey kidney cell cultures.

III-C-1-b-(1)-(b). SV40 DNA, rendered unconditionally defective by a deletion in an essential gene, with an appropriate helper, can be used in P3

conditions to propagate DNA sequences from eukaryotic organisms that do not produce potent polypeptide toxins [34] (shotgun experiments or purified DNA).

III-C-1-b-(1)-(c). Experiments involving the use of defective SV40 genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis [45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-b-(2). *Nonproductive Virus-Cell Interactions*. Defective or whole SV40 genomes can be used as vectors in P2 conditions when production of viral particles cannot occur (e.g., transformation of nonpermissive cells or propagation of an unconditionally defective recombinant genome in the absence of helper), provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis [45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-c. *Human Adenoviruses 2 and 5*.

III-C-1-c-(1). *Productive Virus-Cell Interactions*.

III-C-1-c-(1)-(a). Human adenoviruses 2 and 5, rendered unconditionally defective by deletion of at least two essential genes, with appropriate helper, can be used in P3 conditions to propagate DNA sequences from:

III-C-1-c-(1)-(a)-(1). bacteria of Class 1 or Class 2[1] or their phages or plasmids except for those that produce potent polypeptide toxins; [34]

III-C-1-c-(1)-(a)-(2). eukaryotic organisms that do not produce potent polypeptide toxins[34] (shotgun experiments or purified DNA).

III-C-1-c-(1)-(b). Experiments involving the use of unconditionally defective human adenovirus 2 and 5 genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis [45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-c-(2). *Nonproductive virus-cell interactions*. Defective or whole human adenovirus 2 and 5 genomes can be used as vectors in P2 conditions when production of viral particles cannot occur (e.g., transformation of nonpermissive cells or propagation of an unconditionally defective recombinant genome in the absence of helper), provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis [45] and will be con-

ducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-d. *Murine Adenovirus Strain FL*.

III-C-1-d-(1). *Productive Virus-Cell Interactions*.

III-C-1-d-(1)-(a). Unconditionally defective murine adenovirus strain FL genomes, with appropriate helper, can be used in P2 conditions to propagate DNA sequences from:

III-C-1-d-(1)-(a)-(1). bacteria of Class 1 or Class 2[1] or their phages or plasmids except for those that produce potent polypeptide toxins;[34]

III-C-1-d-(1)-(a)-(2). eukaryotic organisms that do not produce potent polypeptide toxins[34] (shotgun experiments or purified DNA).

III-C-1-d-(1)-(b). Experiments involving the use of whole murine adenovirus strain FL genomes to propagate DNA sequences from prokaryotic or eukaryotic organisms will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-d-(1)-(c). Experiments involving the use of unconditionally defective murine adenovirus strain FL genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-d-(2). *Nonproductive Virus-Cell Interactions*. Defective or whole murine adenovirus strain FL genomes can be used as vectors in P2 conditions when production of viral particles cannot occur (e.g., transformation of nonpermissive cells or propagation of an unconditionally defective recombinant genome in the absence of helper), provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-e. *All Other Potential Viral Vectors*.

III-C-1-e-(1). Experiments involving recombinant DNA molecules containing viral DNA segments consisting of 25% or less of the virus genome can be done:

III-C-1-e-(1)-(a). in P2 conditions when the recombinant DNA is to be integrated into the cell genome or is known to replicate as a plasmid in cells in culture, provided the additional DNA sequences are not derived from a eukaryotic virus. In the latter case, such experiments will be evaluated by NIH on a case-by-case basis [45]

and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-1-e-(1)-(b). Under physical and biological containment conditions to be determined by NIH[45] when a viral helper will be used to propagate DNA sequences from prokaryotic or eukaryotic organisms. (See Section IV-E-1-b-(3)-(c).)

III-C-1-e-(2). Experiments involving the use of other whole or defective virus genomes to propagate DNA sequences from prokaryotic or eukaryotic organisms (and viruses), or as vectors to transform nonpermissive cells, will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

NIH will also review on a case-by-case basis[45] all experiments involving the use of virus vectors in animals and will prescribe the physical and biological containment conditions appropriate for such studies. (See Section IV-E-1-b-(3)-(c).)

III-C-2. *Invertebrate Host-Vector Systems in Which Insect Viruses Are Used to Propagate Other DNA Segments.* As soon as information becomes available on the host range restrictions and on the infectivity, persistence, and integration of the viral DNA in vertebrate and invertebrate cells, experiments involving the use of insect viruses to propagate DNA sequences will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

III-C-3. *Plant Viral Host-Vector Systems.* The DNA plant viruses which could currently serve as vectors and cloning genes in plants and plant cell protoplasts are Cauliflower Mosaic Virus (CaMV) and its close relatives [2A] which have relaxed circular double-stranded DNA genomes with a molecular weight of 4.5×10^6 , and Bean Golden Mosaic Virus (BGMV) and related viruses with small (10^6 daltons) single-stranded DNA genomes. CaMV is spread in nature by aphids, in which it survives for a few hours. Spontaneous mutants of CaMV which lack a factor essential for aphid trans-

mission arise frequently. BGMV is spread in nature by whiteflies, and certain other single-stranded DNA plant viruses are transmitted by leafhoppers.

The DNA plant viruses have narrow host ranges and are relatively difficult to transmit mechanically to plants. For this reason, they are most unlikely to be accidentally transmitted from spillage of purified virus preparations.

When these viruses are used as vectors in intact plants, or propagative plant parts, the plants shall be grown under P1 conditions—that is, in either a limited access greenhouse or plant growth cabinet which is insect-restrictive, preferably with positive air pressure, [2A] and in which an insect fumigation regime is maintained. Soil, plant pots, and unwanted infected materials shall be removed from the greenhouse or cabinet in sealed insect-proof containers and sterilized. It is not necessary to sterilize run-off water from the infected plants, as this is not a plausible route for secondary infection. When the viruses are used as vectors in tissue cultures or in small plants in axenic cultures, no special containment is necessary. Infected plant materials which have to be removed from the greenhouse or cabinet for further research shall be maintained under insect-restrictive conditions. These measures provide an entirely adequate degree of containment. They are similar to those required in many countries for licensed handling of "exotic" plant viruses.

The CaMV strain used as a cloning vector shall be a mutant that lacks the aphid transmission factor.

The viruses or their DNA may also be useful as vectors to introduce genes into plant protoplasts. The fragility of plant protoplasts combined with the properties of the viruses provides adequate safety. Since no risk to the environment from the use of the DNA plant virus/protoplast system is envisaged, no special containment is necessary, except as described in the following paragraph.

Experiments involving the use of plant virus genomes to propagate DNA sequences from eukaryotic viruses will be evaluated by NIH on a case-by-case basis[45] and will be conducted under the prescribed physical and biological containment conditions. (See Section IV-E-1-b-(3)-(c).)

Table IV

Recommended Containment for Recombinant DNA Research Using Eukaryotic Viral Vectors
(See text for full details)

(See text for full details)

Vector DNA	Productive virus-cell interactions							Nonproductive virus-cell interactions [46]
	Prokaryotic			Type of DNA insert			Eukaryotic viral	
	Shotgun	Purified	Eukaryotic					
			Natural host		Other			
			Shotgun	Purified [47]				
1. Polyoma								
Intact Genome	P2	P2		P2	P3	P2	CBC*	P2
Deleted Genome	P2	P2		P2	P2	P2	CBC*	P2
2. SV40								
Intact Genome	---	---		---	---	---	---	P2
Deleted Genome	P2	P2		P2	P3	P3	CBC*	P2
3. Human Ad2+Ad5								
Deleted Genome	P3	P3		P3	P3	P3	CBC*	P2
4. Mouse Adenovirus (Strain FL)								
Intact Genome	CBC*	CBC*		CBC*	CBC*	CBC*	CBC*	P2
Deleted Genome	P2	P2		P2	P2	P2	CBC*	P2
5. Insect Viruses	CBC*	CBC*		CBC*	CBC*	CBC*	CBC*	—
6. Plant Viruses (CaMV and BGW)	**	**		**	**	**	CBC*	—
7. All other potential Viral Vectors	CBC*	CBC*		CBC*	CBC*	CBC*	CBC*	CBC*

*CBC = case-by-case [45]

**See text

III-C-4. *Plant Host-Vector Systems Other than Viruses.* Organelle, plasmid, and chromosomal DNAs may be used as vectors. DNA recombinants formed between such vectors and host DNA, when propagated only in that host (or a closely related strain of the same species), are exempt from these Guidelines (see Section I-E). DNA recombinants formed between such vectors and DNA from cells other than the host species require P2 physical containment. The development of host-vector systems that exhibit a high level of biological containment, such as those using protoplasts or undifferentiated cells in culture, permit [2A] a decrease in the physical containment to P1.

Intact plants or propagative plant parts which cannot be grown in a standard P2 laboratory because of their large size may be grown under the P1 conditions described above in Section III-C-3, except that (i) sterilization of run-off water is required where this is a plausible route for secondary infection and (ii) the standard P2 practices are adopted for microbiological work.

III-C-5. *Fungal or Similar Lower Eukaryotic Host-Vector Systems.* The containment criteria for DNA recombinant experiments using these host-vectors most closely resemble those for prokaryotes, rather than those for the preceding eukaryotes, since the host cells usually exhibit a capacity for dissemination outside the laboratory that is similar to that for bacteria. Therefore, the procedures established for certification of HV systems other than *E. coli* K-12 (Section II-D-2) will also apply to these fungal or similar lower eukaryotic host-vector systems.

Once a HV1 system is approved by NIH, it may be used under P2 containment for shotgun experiments with phages, plasmids, and DNA from Class 1 prokaryotes [1] and lower eukaryotes that do not produce polypeptide toxins. [34] Other classes of recombinant DNA experiments with these HV1 systems will require prior approval and classification by NIH. (See Sections IV-E-1-b-(1)-(b), IV-E-1-b-(2)-(c) and IV-E-1-b-(3)-(b).) If HV2 or HV3 systems of this type are developed and approved by NIH, guidelines for their use in other types of recombinant DNA experiments will also be established.

In addition to the experiments described above, the following experiments may be carried out without the eukaryotic host (Host C) having been approved as an HV1 host: DNA from Host C may be inserted into a vector from a certified EK2 host-vector system and propagated in *E. coli* K-12 under the appropriate containment conditions [see Section III-A-1-(a)-

(5)]. Subsequently, this recombinant DNA may be returned to Host C and propagated there under P1 conditions. [43]

Containment levels for other classes of experiments involving non-HV1 systems may be expressly approved by the Director, NIH. (See Sections IV-E-1-b-(1)-(b), IV-E-1-b-(2)-(c) and IV-E-1-b-(3)-(b).)

III-D. *Complementary DNAs.* Specific containment levels are given in Section III-A-a (see also last column of Table III) for complementary DNA (cDNA) or viral mRNA. For the other Sections of the Guidelines, where applicable, cDNAs synthesized *in vitro* are included within each of the above classifications. For example, cDNAs formed from cellular RNAs that are not purified and characterized are included under III-A-1, shotgun experiments; cDNAs formed from purified and characterized RNAs are included under III-A-3; etc.

Due to the possibility of nucleic acid contamination of enzyme preparations used in the preparation of cDNAs, the investigator must employ purified enzyme preparations that are free of viral nucleic acid.

III-E. *Synthetic DNAs.* If the synthetic DNA segment is likely to [2A] yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent), the containment conditions must be as stringent as would be used for propagating the natural DNA counterpart.

If the synthetic DNA sequence codes for a harmless product, [2A] it may be propagated at the same containment level as its purified natural DNA counterpart. For example, a synthetic DNA segment which corresponds to a non-harmful gene of birds, to be propagated in *E. coli* K-12, would require Ps physical containment plus an EK1 host-vector, or P1 + EK2.

If the synthetic DNA segment is not expressed *in vivo* as a polynucleotide or polypeptide product, the organisms containing the recombinant DNA molecules are exempt [4] from the Guidelines.

IV. RULES AND RESPONSIBILITIES

IV-A. *Policy.* Safety in activities involving recombinant DNA depends on the individual conducting them. The Guidelines cannot anticipate every possible situation. Motivation and good judgement are the key essentials to protection of health and the environment.

The Guidelines are intended to help the Institution, the Institutional Biosafety Committee (IBC), the Biological Safety Officer, and the Principal Investigator determine the safeguards that should be implemented. These Guidelines will never be complete or final, since all conceivable experiments

involving recombinant DNA cannot be foreseen. Therefore, it is the responsibility of the Institution and those associated with it to adhere to the purpose of the Guidelines as well as to their specifics.

Each Institution (and the IBC acting on its behalf is responsible for ensuring that recombinant DNA activities comply with the Guidelines. General recognition of institutional authority and responsibility properly establishes accountability for safe conduct of the research at the local level.

The following roles and responsibilities constitute an administrative framework in which safety is an essential and integral part of research involving recombinant DNA molecules. Further clarifications and interpretations of roles and responsibilities will be issued by NIH as necessary.

IV-B. *General Applicability.* The Guidelines are applicable to all recombinant DNA research within the United States or its territories which is conducted at or sponsored by an Institution that receives any support for recombinant DNA research from NIH. This includes research performed by NIH directly.

An individual receiving support for research involving recombinant DNA must be associated with or sponsored by an Institution that can and does assume the responsibilities assigned in these Guidelines.

The Guidelines are also applicable to projects done abroad if they are supported by NIH funds. If the host country, however, has established rules for the conduct of recombinant DNA projects, then a certificate of compliance with those rules may be submitted to NIH in lieu of compliance with NIH Guidelines. NIH reserves the right to withhold funding if the safety practices to be employed abroad are not reasonably consistent with the NIH Guidelines.

IV-C. *General Definitions.* The following terms, which are used throughout the Guidelines, are defined as follows:

IV-C-1. "DNA" means deoxyribonucleic acid.

IV-C-2. "Recombinant DNA" or "recombinant DNA molecules" means either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules which result from the replication of a molecule described in (i) above.

IV-C-3. "Memorandum of Understanding and Agreement" or "MUA" is a document that (i) provides to NIH or other Federal funding agency an Institution's certification that the recombinant DNA research project complies with the NIH Guidelines and (ii) contains other essential data as required

in the Administrative Practices Supplement.

IV-C-4. "Institution" means any public or private entity (including Federal, State, and local government agencies).

IV-C-5. "Institutional Biosafety Committee" or "IBC" means a committee that (i) meets the requirements for membership specified in Section IV-D-2, and (ii) reviews, approves, and oversees projects in accordance with the responsibilities defined in Section IV-D-2 and -3.

IV-C-6. "NIH Office of Recombinant DNA Activities" or "ORDA" means the office within NIH with responsibility for (i) reviewing and coordinating all activities of NIH related to the Guidelines, and (ii) performing other duties as defined in Section IV-E-3.

IV-C-7. "Recombinant DNA Advisory Committee" or "RAC" means the public advisory committee that advises the Secretary, the Assistant Secretary for Health, and the Director of the National Institutes of Health concerning recombinant DNA research. The RAC shall be constituted as specified in Section IV-E-2.

IV-C-8. "Director, NIH" or "Director" means the Director of the National Institutes of Health and any other officer or employee of NIH to whom authority has been delegated.

IV-C-9. "Federal Interagency Advisory Committee on Recombinant DNA Research" means the committee established in October 1976 to advise the Secretary, HEW, the Assistant Secretary for Health, and the Director, NIH, on the coordination of those aspects of all Federal programs and activities which relate to recombinant DNA research.

IV-C-10. "Administrative Practice Supplement" or "APS" means a publication to accompany the NIH Guidelines specifying administrative procedures for use at NIH and at Institutions.

IV-C-11. "Laboratory Safety Monograph" or "LSM" means a publication to accompany the NIH Guidelines describing practices, equipment, and facilities in detail.

IV-D. *Responsibilities of the Institution*

IV-D-1. Each Institution conducting or sponsoring recombinant DNA research covered by these Guidelines is responsible for ensuring that the research is carried out in full conformity with the provisions of the Guidelines. In order to fulfill this responsibility, the Institution shall:

IV-D-1-a. Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the Guidelines. The Institution, as part of its general responsibilities for imple-

menting the Guidelines, may establish additional procedures, as deemed necessary, to govern the Institution and its components in the discharge of its responsibilities under the Guidelines. This may include (i) statements formulated by the Institution for general implementation of the Guidelines and (ii) whatever additional precautionary steps the Institution may deem appropriate.

IV-D-1-b. Establish an Institutional Biosafety Committee (IBC) that meets the requirements set forth in Section IV-D-2 and carries out the functions detailed in Section IV-D-3.

IV-D-1-c. Submit, for each recombinant DNA project that meets with its approval, a Memorandum of Understanding and Agreement (MUA) to the funding agency for approval and registration. All projects, however, can proceed upon IBC approval (before submission of the MUA to the funding agency) except for the following, which require prior approval by NIH (or other funding agency designated by NIH for this purpose):

IV-D-1-c-(1). Projects for which containment levels are not specified by the Guidelines or NIH,

IV-D-1-c-(2). Projects requiring P4 containment,

IV-D-1-c-(3). Reductions of more than one step in containment levels (see Section III-A-3),

IV-D-1-c-(4). Reductions of containment level for projects involving primate DNA (see Section III-A-3),

IV-D-1-c-(5). Reductions of containment to levels below P1 + EK1 (see Section III-A-3),

IV-D-1-c-(6). The first project conducted in a facility at P3 containment, or

IV-D-1-c-(7). The first project conducted by an Institution.

NOTE: The MUA shall be submitted to the funding agency within 30 days of the IBC approval. If the funding agency does not routinely register recombinant DNA projects with NIH, the MUA must be submitted to NIH as well as to the funding agency. Authority to submit MUAs (or addenda) for which prior approval is not required may be delegated to the IBC chairperson. All MUAs that require NIH approval before the work can proceed shall be submitted to the NIH by the institutional official to whom the IBC is responsible.

IV-D-1-d. Take appropriate action to bring protocols into compliance when advised by NIH or other funding agency that IBC-approved projects do not conform to standards set forth in the Guidelines. This responsibility may be delegated to the IBC. (See Administrative Practices Supplement for further details).

IV-D-1-e. If the Institution is engaged in recombinant DNA research at

the P3 or P4 containment level, appoint a Biological Safety Officer (BSO), who shall be a member of the IBC and carry out the duties specified in Section IV-D-4.

IV-D-1-f. Require that investigators responsible for research covered by these Guidelines comply with the provisions of Section IV-D-5, and assist investigators to do so.

IV-D-1-g. Ensure appropriate training for the IBC chairperson and members, the BSO, Principal Investigators (PIs), and laboratory staff regarding the Guidelines, their implementation, and laboratory safety. Responsibility for training IBC members may be carried out through the IBC chairperson. Responsibility for training laboratory staff may be carried out through the PI. The Institution is responsible for seeing that the PI has sufficient training, but may delegate this responsibility to the IBC.

IV-D-1-h. Determine the necessity, in connection with each project, for health surveillance of recombinant DNA research personnel, and conduct, if found appropriate, a health surveillance program for the project. (The Laboratory Safety Monograph (LSM) discusses various possible components of such a program—for example, records of agents handled, active investigation of relevant illnesses, and the maintenance of serial serum samples for monitoring serologic changes that may result from the employees' work experience. Certain medical conditions may place a laboratory worker at increased risk in any endeavor where infectious agents are handled. Examples given in the LSM include gastrointestinal disorders and treatment with steroids, immunosuppressive drugs, or antibiotics. Workers with such disorders or treatment should be evaluated to determine whether they should be engaged in research with potentially hazardous organisms during their treatment or illness.)

IV-D-1-i. Report within 30 days to ORDA any significant problems with and violations of the Guidelines and significant research-related accidents and illnesses, unless the institution determines that the PI or IBC has done so.

IV-D-2. *Membership and Procedure of the IBC.* The Institution shall establish an Institutional Biosafety Committee (IBC) meeting the following requirements:

IV-D-2-a. The IBC shall comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research experiments and any potential risk to public health or the environment. At least two members (but not less than 20 percent of the mem-

bership of the committee) shall not be affiliated with the Institution (apart from their membership on the IBC) and shall represent the interest of the surrounding community with respect to health and protection of the environment. Members meet this requirement if, for example, they are officials of State or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community. The Biological Safety Officer (BSO), mandatory when research is being conducted at the P3 and P4 levels, shall be a member (see Section IV-D-4).

IV-D-2-b. In order to ensure the professional competence necessary to review recombinant DNA activities, it is recommended that (i) the IBC include persons from disciplines relevant to recombinant DNA technology, biological safety, and engineering; (ii) the IBC include, or have available as consultants, persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment; and (iii) at least one member be a nondoctoral person from a laboratory technical staff.

IV-D-2-c. The Institution shall identify the committee members by name in a report to the NIH Office of Recombinant DNA Activities (ORDA) and shall include relevant background information on each member in such form and at such times as ORDA may require. (See the Administrative Practices Supplement for further guidance.)

IV-D-2-d. No member of an IBC may be involved (except to provide information requested by the IBC) in the review or approval of a project in which he or she has been, or expects to be, engaged or has a direct financial interest.

IV-D-2-e. The Institution may establish procedures that the IBC will follow in its initial and continuing review of applications, proposals, and activities. (IBC review procedures are specified in section IV-D-3-a.)

IV-D-2-f. Central to implementation of the Guidelines is the review of proposed experiments by the IBC. The Institution shall submit, within 30 days of IBC approval, an MUA to NIH (ORDA), or shall otherwise register proposed experiments as specified under Sections IV-D-1-c, IV-D-1-d, and IV-F. In carrying out this responsibility, the Institution shall comply with instructions and procedures specified in the Administrative Practices Supplement.

IV-D-2-g. Institutions are encouraged to open IBC meetings to the public whenever possible, consistent

with protection of privacy and proprietary interests.

IV-D-2-h. Upon request, the Institution shall make available to the public all minutes of IBC meetings and any documents submitted to or received from funding agencies which the latter are required to make available to the public (e.g., MUAs, reports of Guideline violations and significant research-related accidents, and agency directives to modify projects). If comments are made by members of the public on IBC actions, the Institution shall forward to NIH both the comments and the IBC's response.

IV-D-3. *Functions of the IBC.* On behalf of the Institution, the IBC is responsible for:

IV-D-3-a. Reviewing for compliance with the NIH Guidelines all recombinant DNA research to be conducted at or sponsored by the Institution, and approving those research projects that it finds are in conformity with the Guidelines. (See Administrative Practices Supplement, II-D, for prior NIH approval requirements.) This review shall include:

IV-D-3-a-(1). An independent assessment of the containment levels required by these Guidelines for the proposed research, and

IV-D-3-a-(2). An assessment of the facilities, procedures, and practices, and of the training and expertise of recombinant DNA personnel.

NOTE: See Laboratory Safety Monograph (pages 187-190) for suggested guidance in conducting this review.

IV-D-3-b. Authorizing the Principal Investigator (PI) to proceed with the project upon receipt of proper agency approval; or authorizing the PI to proceed without agency approval to initiate or change a project for which none of the exceptions under IV-D-1-e apply.

NOTE: Some examples of work that might ordinarily proceed without prior funding-agency approval are the initiation of a project at the P1 or P2 level (other than the first project at the institution). Other examples are significant changes in hosts or vectors, in the donor species or the nature of the DNA segment selected, or in the physical location of the experiments. Still others are single-step reductions in containment level for (i) experiments with DNA recombinants from cellular DNAs that have been purified and are judged to be free of harmful sequences (see Section III-A-3-a) and for (ii) clones that have been characterized and judged to be free of harmful sequences (see Section III-A-3-b). It should be clear, however, that the funding agency must be notified of IBC approvals even when prior agency approval is not required. See the Administrative Practices Supplement for further discussion.

IV-D-3-c. Reviewing periodically recombinant DNA research being conducted at the Institution, to insure

that the requirements of the Guidelines are being fulfilled.

IV-D-3-d. Adopting emergency plans covering accidental spills and personnel contamination resulting from such research.

NOTE: Basic elements in developing specific procedures for dealing with major spills of potentially hazardous materials in the laboratory are detailed in the Laboratory Safety Monograph. Included are information and references on decontamination and emergency plans. NIH and the Center for Disease Control are available to provide consultation, and direct assistance if necessary, as posted in the LSM. The Institution shall cooperate with the State and local public health departments, reporting any significant research-related illness or accident that appears to be a hazard to the public health.

IV-D-3-e. Reporting within 30 days to the appropriate institutional officials and to the NIH Office of Recombinant DNA Activities (ORDA) any significant problems with or violations of the Guidelines, and any significant research-related accidents or illnesses, unless the IBC determines that the PI has done so.

IV-D-3-f. Performing such other functions as may be delegated to the IBC under Section IV-D-1.

IV-D-4. *Biological Safety Officer.* The Institution shall appoint a BSO if it engages in recombinant DNA research at the P3 or P4 containment level. The officer shall be a member of the Institutional Biosafety Committee (IBC), and his or her duties shall include (but need not be limited to):

IV-D-4-a. Insuring through periodic inspections that laboratory standards are rigorously followed;

IV-D-4-b. Reporting to the IBC and the Institution all significant problems with and violations of the Guidelines and all significant research-related accidents and illnesses of which the BSO becomes aware, unless the BSO determines that the Principal Investigator (PI) has done so.

IV-D-4-c. Developing emergency plans for dealing with accidental spills and personnel contamination, and investigating recombinant DNA research laboratory accidents;

IV-D-4-d. Providing advice on laboratory security;

IV-D-4-e. Providing technical advice to the PI and the IBC on research safety procedures.

NOTE: See Laboratory Safety Monograph for additional information on the duties of the BSO.

IV-D-5. *Principal Investigator.* On behalf of the Institution, the PI is responsible for complying fully with the Guidelines in conducting any recombinant DNA research.

IV-D-5-a. *PI-General.* As part of this general responsibility, the PI shall:

IV-D-5-a-(1). Initiate or modify no recombinant DNA research subject to the Guidelines until that research, or the proposed modification thereof, has been approved by the Institutional Biosafety Committee (IBC) and has met all other requirements of the Guidelines and the Administrative Practices Supplement (APS), and make changes to conform if the NIH Office of Recombinant DNA Activities' (ORDA's) review so requires;

IV-D-5-a-(2). Report within 30 days to the IBC and NIH (ORDA) all significant problems with and violations of the Guidelines and all significant research-related accidents and illnesses;

IV-D-5-a-(3). Report to the IBC and to NIH (ORDA) new information bearing on the Guidelines;

IV-D-5-a-(4). Be adequately trained in good microbiological techniques;

IV-D-5-a-(5). Adhere to IBC-approved emergency plans for dealing with accidental spills and personnel contamination; and

IV-D-5-a-(6). Comply with shipping requirements for recombinant DNA molecules. (See Section II-C for shipping requirements, Laboratory Safety Monograph for technical recommendations, and the APS for administrative instructions and procedures. The requesting laboratory must be in compliance with the NIH Guidelines and under appropriate review by its IBC, and the sending investigator must maintain a record of all shipments of recombinant DNA materials.)

IV-D-5-b. *Submissions by the PI to NIH.* The PI shall:

IV-D-5-b-(1). Submit information to NIH (ORDA) in order to have new host-vector systems certified;

IV-D-5-b-(2). Petition NIH, with notice to the IBC, for exemptions to these Guidelines (see Sections I-E-4 and I-E-5 and, for additional information on procedures, the APS); and

IV-D-5-b-(3). Petition NIH, with concurrence of the IBC, for exceptions to the prohibitions under these Guidelines (see Section I-D and, for additional information on procedures, the APS).

IV-D-5-c. *Submissions by the PI to the IBC.* The PI shall:

IV-D-5-c-(1). Make the initial determination of the required levels of physical and biological containment in accordance with the Guidelines;

IV-D-5-c-(2). Select appropriate microbiological practices and laboratory techniques to be used in the research;

IV-D-5-c-(3). Submit the initial research protocol (and also subsequent changes—e.g., changes in the source of DNA or host-vector system, which require a new or revised Memorandum of Understanding and Agreement) to the IBC for review and approval or disapproval; and

IV-D-5-c-(4). Remain in communication with the IBC throughout the conduct of the project.

IV-D-5-d. *PI Responsibilities After Approval but Prior to Initiating the Research.* The PI is responsible for:

IV-D-5-d-(1). Making available to the laboratory staff copies of the approved protocols that describe the potential biohazards and the precautions to be taken;

IV-D-5-d-(2). Instructing and training staff in the practices and techniques required to ensure safety and in the procedures for dealing with accidents; and

IV-D-5-d-(3). Informing the staff of the reasons and provisions for any precautionary medical practices advised or requested, such as vaccinations or serum collection.

IV-D-5-e. *PI Responsibilities During the Conduct of the Approved Research.* The PI is responsible for:

IV-D-5-e-(1). Supervising the safety performance of the staff to ensure that the required safety practices and techniques are employed;

IV-D-5-e-(2). Investigating and reporting in writing to ORDA, the Biological Safety Officer (where applicable), and the IBC any significant problems pertaining to the operation and implementation of containment practices and procedures;

IV-D-5-e-(3). Correcting work errors conditions that may result in the release of recombinant DNA materials;

IV-D-5-e-(4). Ensuring the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity, and genotypic and phenotypic characteristics); and

IV-D-5-e-(5). *Publications.* PIs are urged to include, in all publications reporting on recombinant DNA research, a description of the physical and biological containment procedures employed.

IV-E. *Responsibilities of NIH*

IV-E-1. *Director.* The Director, NIH, is responsible for (i) establishing the NIH Guidelines in recombinant DNA research, (ii) overseeing their implementation, and (iii) their final interpretation.

The Director has a number of responsibilities under the Guidelines that involve the NIH Office of Recombinant DNA Activities (ORDA) and the Recombinant DNA Advisory Committee (RAC). ORDA's responsibilities under the Guidelines are administrative. Advice from the RAC is primarily scientific and technical. In certain circumstances, there is specific opportunity for public comment, with published response, before final action.

IV-E-1-a. *General Responsibilities of the Director, NIH.* The responsibilities of the Director shall include the following:

IV-E-1-a-(1). Promulgating requirements as necessary to implement the Guidelines;

IV-E-1-a-(2). Establishing and maintaining the RAC to carry out the responsibilities set forth in Section IV-E-2. The RAC's membership is specified in its charter and in Section IV-E-2.

IV-E-1-a-(3). Establishing and maintaining ORDA to carry out the responsibilities defined in Section IV-E-3; and

IV-E-1-a-(4). Maintaining the Federal Interagency Advisory Committee on Recombinant DNA Research established by the Secretary, HEW, for advice on the coordination of all Federal programs and activities relating to recombinant DNA, including activities of the RAC.

IV-E-1-b. *Specific Responsibilities of the Director, NIH.* In carrying out the responsibilities set forth in this Section, the Director shall weigh each proposed action, through appropriate analysis and consultation, to determine that it complies with the Guidelines and presents no significant risk to health or the environment.

IV-E-1-b-(1). *The Director is responsible for the following major actions* (For these, the Director must seek the advice of the RAC and provide an opportunity for public and Federal agency comment. Specifically, the agenda of the RAC meeting citing the major actions will be published in the FEDERAL REGISTER at least 30 days before the meeting, and the Director will also publish the proposed actions in the FEDERAL REGISTER for comment at least 30 days before the meeting. In addition, the Director's proposed decision, at his discretion, may be published in the FEDERAL REGISTER for 30 days of comment before final action is taken. The Director's final decision, along with response to the comments, will be published in the FEDERAL REGISTER and the *Recombinant DNA Technical Bulletin*. The RAC and IBC chairpersons will be notified of this decision):

IV-E-1-b-(1)-(a). Changing containment levels for types of experiments that are specified in the Guidelines when a major action is involved;

IV-E-1-b-(1)-(b). Assigning containment levels for types of experiments that are not explicitly considered in the Guidelines when a major action is involved;

IV-E-1-b-(1)-(c). Certifying new host-vector systems, with the exception of minor modifications of already certified systems [The standards and procedures for certification are described in Section II-D-2-a. Minor modifications constitute, for example, those of minimal or no consequence to the properties relevant to containment. See the Administrative Prac-

tics Supplement (APS) for further information];

IV-E-1-b-(1)-(d). Promulgating and amending a list of classes of recombinant DNA molecules to be exempt from these Guidelines because they consist entirely of DNA segments from species that exchange DNA by known physiological processes, or otherwise do not present a significant risk to health or the environment (see Sections I-E-4 and -5 and the APS for further information);

IV-E-1-b-(1)-(e). Permitting exceptions to the prohibited experiments in the Guidelines, in order, for example, to allow risk-assessment studies; and

IV-E-1-b-(1)-(f). Adopting other changes in the Guidelines.

IV-E-1-b-(2). *The Director is also responsible for the following lesser actions.* (For these, the Director must seek the advice of the RAC. The Director's decision will be transmitted to the RAC and IBC chairpersons and published in the *Recombinant DNA Technical Bulletin*);

IV-E-1-b-(2)-(a). Interpreting and determining containment levels, upon request by ORDA;

IV-E-1-b-(2)-(b). Changing containment levels for experiments that are specified in the Guidelines (see Section III);

IV-E-1-b-(2)-(c). Assigning containment levels for experiments not explicitly considered in the Guidelines (see Section III); and

IV-E-1-b-(2)-(d). Designating certain class 2 agents as class 1 for the purpose of these Guidelines (see Footnote 1 and Appendix B).

IV-E-1-b-(3). *The Director is also responsible for the following actions* (The Director's decision will be transmitted to the RAC and IBC chairpersons and published in the *Recombinant DNA Technical Bulletin*);

IV-E-1-b-(3)-(a). Interpreting the Guidelines for experiments to which the Guidelines specifically assign containment levels;

IV-E-1-b-(3)-(b). Determining appropriate containment conditions for experiments according to case procedure developed under Section IV-E-1-b-(2)-(c).

IV-E-1-b-(3)-(c). Determining appropriate containment conditions upon case-by-case analysis of experiments explicitly considered in the Guidelines but for which no containment levels have been set (see Footnote 45 in Part V; Sections III-C-1-a through -e; and Sections III-C-2 and -3);

IV-E-1-b-(3)-(d). Authorizing, under procedures specified by the RAC, large-scale experiments (i.e., involving more than 10 liters of culture) for recombinant DNAs that are rigorously characterized and free of harmful se-

quences (see Footnote 3 and Section I-D-6);

IV-E-1-b-(3)-(e). Lowering containment levels one step for characterized clones involving primate DNA or for experiments using purified primate DNA (see Sections III-A-3-a and -b, and Footnotes 3 and 41);

IV-E-1-b-(3)-(f). Lowering containment levels for experiments involving other characterized clones or purified DNA below P1 + EK1 (see Sections III-A-3-a and -b, and Footnotes 3 and 41);

IV-E-1-b-(3)-(g). Lowering containment levels for characterized clones or purified DNA beyond one step (see Sections III-A-3-a and -b, and Footnotes 3 and 41);

IV-E-1-b-(3)-(h). Approving minor modifications of already certified host-vector systems (The standards and procedures for such modifications are described in Section II-D-2-a); and

IV-E-1-b-(3)-(i). Decertifying already certified host-vector systems.

IV-E-1-b-(4). The Director shall conduct, support, and assist training programs in laboratory safety for Institutional Biosafety Committee members, Biological Safety Officers, Principal Investigators, and laboratory staff.

IV-E-1-b-(5). The Director, at the end of 36 months from the time these Guidelines are promulgated, will report on the Guidelines, their administration, and the potential risks and benefits of this research. In doing so, the Director will consult with the RAC and the Federal Interagency Committee. Public comment will be solicited on the draft report and taken into account in transmitting the final report to the Assistant Secretary for Health and the Secretary, HEW.

IV-E-2. *Recombinant Advisory Committee.* The NIH Recombinant DNA Advisory Committee (RAC) is responsible for carrying out specified functions cited below as well as others assigned under its charter or by the Secretary, HEW, the Assistant Secretary for Health, and the Director, NIH.

The members of the committee shall be chosen to provide, collectively, expertise in scientific fields relevant to recombinant DNA technology and biological safety—e.g., microbiology, molecular biology, virology, genetics, epidemiology, infectious diseases, the biology of enteric organisms, botany, plant pathology, ecology, and tissue culture. At least 20 percent of the members shall be persons knowledgeable in applicable law, standards of professional conduct and practice, public attitudes, the environment, public health, occupational health, or related fields. Representatives from Federal agencies shall serve as nonvoting members. Nominations for the RAC may be submitted to the NIH

Office of Recombinant DNA Activities.

All meetings of the RAC will be announced in the *FEDERAL REGISTER*, including tentative agenda items, 30 days in advance of the meeting, with final agendas (if modified) available at least 72 hours before the meeting. No item defined as a major action under Section IV-E-1-b-(1) may be added to an agenda after it appears in the *FEDERAL REGISTER*.

IV-E-2-a. *The RAC shall be responsible for advising the Director, NIH, on the actions listed in Section IV-E-1-b-(1) and -(2).*

IV-E-3. *The Office of Recombinant DNA Activities.* ORDA shall serve as a focal point for information on recombinant DNA activities and provide advice to all within and outside NIH, including Institutions, Biological Safety Committees, Principal Investigators, Federal agencies, State and local governments, and institutions in the private sector. ORDA shall carry out such other functions as may be delegated to it by the Director, NIH, including those authorities described in Section IV-E-1-b-(3). In addition, ORDA shall be responsible for the following:

IV-E-3-a. Review and approval of Institutional Biosafety Committee (IBC) membership;

IV-E-3-b. Registration of recombinant DNA projects; and

IV-E-3-c. Review of Memoranda of Understanding and Agreement (MUAs), and approval of those that conform to the Guidelines. In so doing, ORDA shall:

IV-E-3-c-(1). Conduct an independent evaluation of the containment levels required for the research covered by these Guidelines;

IV-E-3-c-(2). Determine whether the physical and biological containment levels approved by the IBC are in accordance with the requirement of the Guidelines;

IV-E-3-c-(3). Notify Institutions and the IBC chairperson in a timely fashion when MUAs (including changes in ongoing projects) do not conform to the Guidelines, and inform them of corrective measures to be taken;

IV-E-3-c-(4). Publish in the *FEDERAL REGISTER*:

IV-E-3-c-(4)-(a). Announcements of Recombinant DNA Advisory Committee (RAC) meetings and agendas 30 days in advance, with publication of the Director's proposed decision for 30 days of public and Federal agency comment followed by a published response, on any action listed in Section IV-E-1-b-(1); and

IV-E-3-c-(4)-(b). Announcements of RAC meetings and agendas 30 days in advance on any action listed in Section IV-E-1-b-(2).

NOTE.—If the agenda for an RAC meeting is modified, ORDA shall make the revised agenda available to anyone, upon request, at least 72 hours in advance of the meeting.

IV-E-3-c-(5). Publish the *Recombinant DNA Technical Bulletin*; and

IV-E-3-c-(6). Serve as executive secretary to the RAC.

IV-E-4. Other NIH Components. Other NIH components shall be responsible for:

IV-E-4-a. Awarding no grant or contract involving recombinant DNA techniques unless a properly executed MUA has been received;

IV-E-4-b. Certifying P4 facilities, inspecting them periodically and inspection other recombinant DNA facilities as deemed necessary; and

IV-E-4-c. Announcing and distributing certified HV2 and HV3 host-vector systems (see Section II-E-3).

(See Administrative Practices Supplement for additional information on the administrative procedures of ORDA and other NIH components.)

IV-F. Registration

IV-F-1. Required Registration. Institutions receiving NIH funds for recombinant DNA projects shall inform NIH of all recombinant DNA projects at the institution. A non-NIH project, after approval by the Institutional Biosafety Committee, shall be registered with NIH within 30 days of initiation. Applications for NIH projects must be accompanied by a Memorandum of Understanding and Agreement (MUA).

For information on MUAs or equivalent documents that must be submitted for registration of recombinant DNA projects, see the Administrative Practices Supplement (APS).

IV-F-2. Federal Agency Registration. Institutions at which recombinant DNA research projects funded by other Federal agencies are conducted need not register such projects with NIH when the Federal agency maintains a registry and provides such information to NIH. Registration of non-NIH-funded research with the NIH Office of Recombinant DNA Activities (ORDA) is described in the APS. (The information required is similar to that in an MUA for NIH-supported research.)

IV-F-3. Voluntary Registration and Certification. Any institution that is not required to comply with the Guidelines may nevertheless register recombinant DNA research projects with NIH by submitting the appropriate information to ORDA. NIH will accept requests for certification of host-vector systems proposed by the institution. The submitter must agree to abide by the physical and biological containment standards of the NIH Guidelines.

IV-F-4. Disclosure of Information. Institutions are reminded that they

should consider applying for a patent before submitting information to DHEW which they regard as potentially proprietary. (Provisions for protection of proprietary information as permitted under current DHEW authorities will be proposed as a future supplement to these Guidelines.)

IV-G. Compliance. As a condition for NIH funding of recombinant DNA research, Institutions must ensure that such research conducted at or sponsored by the Institution, irrespective of the source of funding, shall comply with these Guidelines. The policies on noncompliance are as follows:

IV-G-1. All NIH-funded projects involving recombinant DNA techniques must comply with the NIH Guidelines. Noncompliance may result in (i) suspension, limitation, or termination of financial assistance for such projects and of NIH funds for other recombinant DNA research at the Institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the Institution.

IV-G-2. All non-NIH-funded projects involving recombinant DNA techniques conducted at or sponsored by an Institution that receives NIH funds for projects involving such techniques must comply with the NIH Guidelines. Noncompliance may result in (i) suspension, limitation, or termination of NIH funds for recombinant DNA research at the Institution, or (ii) a requirement for prior NIH approval of any or all recombinant DNA projects at the Institution.

IV-G-3. Information concerning noncompliance with the Guidelines may be brought forward by any person. It should be delivered to both NIH (ORDA) and the relevant Institution. The Institution, generally through the IBC, shall take appropriate action. The Institution shall forward a complete report of the incident to ORDA, recommending any further action indicated.

IV-G-4. In cases where NIH proposes to suspend, limit, or terminate financial assistance because of noncompliance with the Guidelines, applicable DHEW and Public Health Service procedures shall govern.

V. FOOTNOTES AND REFERENCES

1. The reference to organisms as Class 1, 2, 3, 4, or 5 refers to the classification in the publication *Classification of Etiologic Agents on the Basis of Hazard*, 4th Edition, July 1974; U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, Office of Biosafety, Atlanta, Georgia 30333. The list of organisms in each class, as given in this publication, is reprinted in Appendix B to these Guidelines.

The Director, NIH, with advice of the Recombinant DNA Advisory Committee, may designate certain of the agents which are listed as Class 2 in the *Classification of Etiologic Agents on the Basis of Hazard*, 4th

Edition, July 1974, as Class 1 agents for the purposes of these Guidelines (see Section IV-E-1-b-(2)-(d)). An updated list of such agents may be obtained from the Office of Recombinant DNA Activities (ORDA), National Institutes of Health, Bethesda, Maryland 20014.

The entire *Classification of Etiologic Agents on the Basis of Hazard* is in the process of revision.

One exception to the prohibition of formation of recombinant DNAs derived from Class 3, 4, or 5 agents is that the formation of recombinant DNAs derived from Vesicular Stomatitis Virus (VSV) is not prohibited. The reason for this is explained in the "Decision Document" accompanying the proposed revised guidelines published in the FEDERAL REGISTER on July 28, 1978. However, as noted in Appendix B, a permit from the U.S. Department of Agriculture is required for the import or interstate transport of VSV. This can be obtained from USDA-APHIS, Veterinary Service, Federal Building, Hyattsville, Maryland 20782.

2A. In Parts I and III of the Guidelines, there are a number of places where judgments are to be made. These include: "cells known to be infected with such agents" (Section I-D-1); "toxins potent for vertebrates" (Section I-D-2); "beyond that which occurs by natural genetic exchange" (Section I-D-3); "known to acquire it naturally" (Section I-D-5); "known to produce a potent polypeptide toxin * * * or known to carry such pathogens * * * not likely to be a product of closely linked eukaryote genes * * * shown not to contain such agents" (Section III-A-1-a-(5)-(a)); "shown to be free of disease causing microorganisms" (Section III-A-1-a-(5)-(b)); "close relatives" (Section III-C-3); and "produce a potent polypeptide toxin" (Footnote 34).

In all these cases the principal investigator is to make the initial judgment on these matters as part of his responsibility to "make the initial determination of the required levels of physical and biological containment in accordance with the Guidelines" (Section IV-D-7-a). In all these cases, this judgment is to be reviewed and approved by the Institutional Biosafety Committee as part of its responsibility to make "an independent assessment of the containment levels required by these Guidelines for the proposed research" (Section IV-D-3-a-(1)). If the IBC wishes, any specific cases may be referred to the NIH Office of Recombinant DNA Activities as part of ORDA's functions to "provide advice to all within and outside NIH" (Section IV-E-3), and ORDA may request advice from the Recombinant DNA Advisory Committee as part of the RAC's responsibility for "interesting and determining containment levels upon request by ORDA" (Section IV-E-1-b-(2)-(a)).

3. The following types of data should be considered in determining whether DNA recombinants are "characterized" and the absence of harmful sequences has been established: (a) The absence of potentially harmful genes (e.g., sequences contained in indigenous tumor viruses or sequences that code for toxins, invasins, virulence factors, etc., that might potentiate the pathogenicity or communicability of the vector and/or the host or be detrimental to humans, animals, or plants); (b) the type(s) of genetic information on the cloned segment and the nature of transcriptional and translation gene products specified; (c) the relationship

between the recovered and desired segment (e.g., hybridization and restriction endonuclease fragmentation analysis where applicable); (d) the genetic stability of the cloned fragment; and (e) any alterations in the biological properties of the vector and host.

4. In Section I-E, "exemptions" from the Guidelines are discussed. Such exemptions are not covered by the Guidelines and need not be registered with NIH. In Section I-D on "prohibitions," the possibility of "exceptions" is discussed. An "exception" means that an experiment may be expressly released from a prohibition. At that time it will be assigned appropriate

5. Care should be taken to inactivate recombinant DNA before disposal. Procedures for inactivating DNA can be found in the "Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research."

6. *Laboratory Safety at the Center for Disease Control* (Sept. 1974). U.S. Department of Health, Education and Welfare Publication No. CDC 75-8118.

7. *Classification of Etiologic Agents on the Basis of Hazard*. (4th Edition, July 1974). U.S. Department of Health, Education and Welfare, Public Health Service, Center for Disease Control, Office of Biosafety, Atlanta, Georgia 30333.

8. *National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses* (Oct. 1974). U.S. Department of Health, Education and Welfare Publication No. (NIH) 75-790.

9. *National Institutes of Health Biohazards Safety Guide* (1974). U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health. U.S. Government Printing Office, Stock No. 1740-00383.

10. *Biohazards in Biological Research* (1973). A. Hellman, M. N. Oxman, and R. Pollack (ed.). Cold Spring Harbor Laboratory.

11. *Handbook of Laboratory Safety* (1971). Second Edition. N. V. Steere (ed.). The Chemical Rubber Co., Cleveland.

12. Bodily, H. L. (1970). *General Administration of the Laboratory*. H. L. Bodily, E. L. Updyke, and J. O. Mason (eds.). Diagnostic Procedures for Bacterial, Mycotic and Parasitic Infections. American Public Health Association, New York, pp. 11-28.

13. Darlow, H. M. (1969). *Safety in the Microbiological Laboratory*. In J. R. Norris and D. W. Robbins (ed.), *Methods in Microbiology*. Academic Press, Inc. New York, pp. 169-204.

14. *The Prevention of Laboratory Acquired Infection* (1974). C. H. Collins, E. G. Hartley, and R. Plisworth. Public Health Laboratory Service, Monograph Series No. 6.

15. Chatigny, M. A. (1961). *Protection Against Infection in the Microbiological Laboratory: Devices and Procedures*. In W. W. Umbreit (ed.), *Advances in Applied Microbiology*. Academic Press, New York, N.Y. 3:131-192.

16. *Design Criteria for Viral Oncology Research Facilities* (1975). U.S. Department of Health, Education and Welfare, Public Health Service, National Institutes of Health, DHEW Publication No. (NIH) 75-891.

17. Kuehne, R. W. (1973). *Biological Containment Facility for Studying Infectious Disease*. Appl. Microbiol. 26:239-243.

18. Runkle, R. S., and G. B. Phillips (1969). *Microbial Containment Control*

Facilities. Van Nostrand Reinhold, New York.

19. Chatigny, M. A., and D. I. Clinger (1969). *Contamination Control in Aerobiology*. In R. L. Dimmick and A. B. Akers (eds.), *An Introduction to Experimental Aerobiology*. John Wiley & Sons, New York, pp. 194-263.

19A Horsfall, F. L., Jr., and J. H. Baner (1940). *Individual Isolation of Infected Animals in a Single Room*. J. Bact. 40, 569-580.

20. Biological safety cabinets referred to in this section are classified as *Class I*, *Class II*, or *Class III* cabinets. A *Class I* is a ventilated cabinet for personnel protection having an inward flow of air away from the operator. The exhaust air from this cabinet is filtered through a high-efficiency particulate air (HEPA) filter. This cabinet is used in three operational modes: (1) With a full-width open front, (2) with an installed front closure panel (having four 8-inch diameter openings) without gloves, and (3) with an installed front closure panel equipped with arm-length rubber gloves. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. A *Class II* cabinet is a ventilated cabinet for personnel and product protection having an open front with inward air flow for personnel protection, and HEPA filtered mass recirculated air flow for product protection. The cabinet exhaust air is filtered through a HEPA filter. The face velocity of the inward flow of air through the full-width open front is 75 feet per minute or greater. Design and performance specifications for *Class II* cabinets have been adopted by the National Sanitation Foundation, Ann Arbor, Michigan. A *Class III* cabinet is a closed-front ventilated cabinet of gas-tight construction which provides the highest level of personnel protection of all biohazard safety cabinets. The interior of the cabinet is protected from contaminants exterior to the cabinet. The cabinet is fitted with arm-length rubber gloves and is operated under a negative pressure of at least 0.5 inches water gauge. All supply air is filtered through HEPA filters. Exhaust air is filtered through two HEPA filters or one HEPA filter and incinerator before being discharged to the outside environment.

21. Hershfield, V., H. W. Boyer, C. Yanofsky, M. A. Lovett, and D. R. Helinski (1974). *Plasmid Col El as a Molecular Vehicle for Cloning and Amplification of DNA*. Proc. Nat. Acad. Sci. USA 71, 3455-3459.

22. Wensink, P. C., D. J. Finnegan, J. E. Donelson, and D. S. Hogness (1974). *A System for Mapping DNA Sequences in the Chromosomes of Drosophila melanogaster*. Cell 3, 315-335.

23. Tanaka, T., and B. Weisblum (1975). *Construction of a Colicin El-R Factor Composite Plasmid In Vitro: Means for Amplification of Deoxyribonucleic Acid*. J. Bacteriol. 121, 354-362.

24. Armstrong, K. A., V. Hershfield, and D. R. Helinski (1977). *Gene Cloning and Containment Properties of Plasmid Col El and Its Derivatives*. Science 196, 172-174.

25. Bolivar, F., R. L. Rodriguez, M. C. Betlach, and H. W. Boyer (1977). *Construction and Characterization of New Cloning Vehicles: I. Ampicillin-Resistant Derivative of pMB9*. Gene 2, 75-93.

26. Cohen, S. N., A. C. W. Chang, H. Boyer, and R. Helling (1973). *Construction of Biologically Functional Bacterial Plasmids In Vitro*. Proc. Natl. Acad. Sci. USA 70, 3240-3244.

27. Bolivar, F., R. L. Rodriguez, R. J. Greene, M. C. Batlach, H. L. Reyneker, H. W. Boyer, J. H. Crosa, and S. Falkow (1977). *Construction and Characterization of New Cloning Vehicles: II. A Multi-Purpose Cloning System*. Gene 2, 95-113.

28. Thomas, M., J. R. Cameron, and R. W. Davis (1974). *Viable Molecular Hybrids of Bacteriophage Lambda and Eukaryotic DNA*. Proc. Nat. Acad. Sci. USA 71, 4579-4583.

29. Murray, N. E., and K. Murray (1974). *Manipulation of Restriction Targets in Phage Lambda to Form Receptor Chromosomes for DNA Fragments*. Nature 251, 476-481.

30. Rambach, A., and P. Tiollais (1974). *Bacteriophage Having EcoRI Endonuclease Sites Only in the Non-Essential Region of the Genome*. Proc. Nat. Acad. Sci. USA 71, 3927-3930.

31. Blattner, F. R., B. G. Williams, A. E. Bleche, K. Denniston-Thompson, H. E. Faber, L. A. Furlong, D. J. Gunwald, D. O. Kiefer, D. D. Moore, J. W. Shumm, E. L. Sheldon, and O. Smithies (1977). *Charon Phages: Safer Derivatives of Bacteriophage Lambda for DNA Cloning*. Science 196, 163-169.

32. Donoghue, D. J., and P. A. Sharp (1977). *An Improved Lambda Vector: Construction of Model Recombinants Coding for Kanamycin Resistance*. Gene 1, 209-227.

33. Leder, P., D. Tiemeier, and L. Enquist (1977). *EK2 Derivatives of Bacteriophage Lambda Useful in the Cloning of DNA from Higher Organisms: The gt WES System*. Science 196, 175-177.

33A. Skalka, A. (1978). *Current Status of Coliphage EK2 Vectors*. Gene 3, 29-35.

33B. Szybalski, W., A. Skalka, S. Gottesman, A. Campbell, and D. Botstein (1978). *Standardized Laboratory Tests for EK2 Certification*. Gene 3, 36-38.

34. We are specifically concerned with the remote possibility that potent toxins could be produced by acquiring a single gene or cluster of genes. See also footnote 2A.

35. Defined as observable under optimal laboratory conditions by transformation, transduction, phage infection, and/or conjugation with transfer of phage, plasmid, and/or chromosomal genetic information. Note that this definition of exchange may be less stringent than that applied to exempt organisms under Section I-E-4.

36. As classified in the Second Report of the International Committee on Taxonomy of Viruses: Classification and Nomenclature of Viruses, Frank Fenner, Ed. Intervirology 7 (19-115) 1976. (As noted in the Prohibition Section, the use of viruses classified [1] as Class 3, 4, or 5, other than VSV, is prohibited.)

37. The cDNA copy of the viral mRNA must be >99% pure; otherwise as for shotgun experiments with eukaryotic cellular DNA.

37A. For the purpose of these Guidelines, viruses of the families Papovaviridae, Adenoviridae, and Herpesviridae (36) should be considered as "transforming" viruses. While only certain of these viruses have been associated with cell transformation *in vivo* or *in vitro*, it seems prudent to consider all members to be potentially capable of transformation. In addition, those viruses of the family Porviridae that produce proliferative responses—i.e., myxoma, rabbit and squirrel fibroma, and Yaba viruses—should be considered as "transforming."

38. >99% pure (i.e., less than 1% of the DNA consists of intact viral genomes); otherwise as for whole genomes.

39. The viruses have been classified by NCI as "moderate-risk oncogenic viruses." See "Laboratory Safety Monograph—A Supplement to the NIH Guidelines for Recombinant DNA Research" for recommendations on handling the viruses themselves.

40. EK1CV means the use of an EK1 host and a vector certified for use in an EK2 system.

41. The DNA preparation is defined as "purified" if the desired DNA represents at least 99% (w/w) of the total DNA in the preparation, provided that it was verified by more than one procedure.

42. The lowering of the containment level when this degree of purification has been obtained is based on the fact that the total number of clones that must be examined to obtain the desired clone is markedly reduced. Thus, the probability of cloning a harmful gene could, for example, be reduced by more than 10-fold when a nonrepetitive gene from mammals was being sought. Furthermore, the level of purity specified here makes it easier to establish that the desired DNA does not contain harmful genes.

43. This is not permitted, of course, if it falls under any of the Prohibitions of Section I-D. Of particular concern here is prohibition I-D-5, i.e., "Deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire it naturally, if such acquisition could compromise the use of a drug to control disease agents in human or veterinary medicine or agriculture."

44. Because this work will be done almost exclusively in tissue culture cells, which have no capacity for propagation outside the laboratory, the primary focus for containment is the vector. It should be pointed out that risk of laboratory-acquired infection as a consequence of tissue culture manipulation is very low. Given good microbiological practices, the most likely mode of escape of recombinant DNAs from a physically contained laboratory is carriage by an infected human. Thus the vector with an inserted DNA segment should have little or no ability to replicate or spread in humans.

For use as a vector in a vertebrate host cell system, an animal viral DNA molecule should display the following properties:

(i) It should not consist of the whole genome of any agent that is infectious for humans or that replicates to a significant extent in human cells in tissue culture. If the recombinant molecule is used to transform nonpermissive cells (i.e., cells which do not produce infectious virus particles), this is not a requirement.

(ii) It should be derived from a virus whose epidemiological behavior and host range are well understood.

(iii) In permissive cells, it should be defective when carrying an inserted DNA segment (i.e., propagation of the recombinant DNA as a virus must be dependent upon the presence of a complementing helper genome). In almost all cases this condition would be achieved automatically by the manipulations used to construct and propagate the recombinants. In addition, the amount of DNA encapsidated in the particles of most animal viruses is defined within fairly close limits. The insertion of sizable foreign DNA sequences, therefore, generally demands a compensatory deletion of viral sequences. It may be possible to introduce

very short insertions (50-100 base pairs) without rendering the viral vector defective. In such a situation, the requirement that the viral vector be defective is not necessary, except in those cases in which the inserted DNA encodes a biologically active polypeptide.

It is desired but not required that the functional anatomy of the vector be known—that is, there should be a clear idea of the location within the molecule of:

- (i) The sites at which DNA synthesis originates and terminates,
- (ii) The sites that are cleaved by restriction endonucleases, and
- (iii) The template regions for the major gene product.

If possible the helper virus genome should: (i) Be integrated into the genome of a stable line of host cells (a situation that would effectively limit the growth of the vector recombinant to such cell lines) or

(ii) Consist of a defective genome, or an appropriate conditional lethal mutant virus, making vector and helper dependent upon each other for propagation.

However, neither of these stipulations is a requirement.

45. Review by NIH on a case-by-case basis means that NIH must review and set appropriate containment conditions before the work may be undertaken. NIH actions in such case-by-case reviews will be published in the *Recombinant DNA Technical Bulletin*.

46. Provided the inserted DNA sequences are not derived from eukaryotic viruses. In the latter case, such experiments will be evaluated on a case-by-case basis.

47. >99% pure; otherwise as for shotgun experiments.

APPENDIX A

Section I-E-4 states that exempt from these Guidelines are "certain specified recombinant DNA molecules that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the Director, NIH, with advice of the Recombinant DNA Advisory Committee, after appropriate notice and opportunity for public comment (see Section IV-E-1-b-(1)-(d)). Certain classes are exempt as of publication of these Revised Guidelines. The list is in Appendix A."

Under exemption I-E-4 of these revised Guidelines are recombinant DNA molecules that are (1) composed entirely of DNA segments from one or more of the organisms of the following classes, and (2) to be propagated in any of the organisms listed below. (Classification of *Bergey's Manual of Determinative Bacteriology*, eighth edition. R. E. Buchanan and N. E. Gibbons, editors. Williams and Wilkins Company: Baltimore, 1974.)

1. Genus *Escherichia*
2. Genus *Shigella*
3. Genus *Salmonella* (including *Arizona*)
4. Genus *Enterobacter*
5. Genus *Citrobacter* (including *Levinea*)
6. Genus *Klebsiella*
7. *Erwinia amylovora*
8. *Pseudomonas aeruginosa*
9. *Serratia marcescens*

APPENDIX B

CLASSIFICATION OF MICROORGANISMS ON THE BASIS OF HAZARD

I. Classification of Etiologic Agents on the Basis of Hazard (1)

A. Class 1 Agents

All bacterial, parasitic, fungal, viral, rickettsial, and chlamydial agents not included in higher classes.

B. Class 2 Agents

1. Bacterial Agents

Actinobacillus—all species except *A. mallei*, which is in Class 3
Arizona hinshawii—all serotypes
Bacillus anthracis
Bordetella—all species
Borrelia recurrentis, *B. vincenti*
Clostridium botulinum, *Cl. chauvoei*, *Cl. haemolyticum*, *Cl. histolyticum*, *Cl. novyi*, *Cl. septicum*, *Cl. tetani*
Corynebacterium diphtheriae, *C. equi*, *C. haemolyticum*, *C. pseudotuberculosis*, *C. pyogenes*, *C. renale*
Diplococcus (Streptococcus) pneumoniae
Erysipelothrix insidiosa
Escherichia coli—all enteropathogenic serotypes
Haemophilus ducreyi, *H. influenzae*
Herellae vaginicola
Klebsiella—all species and all serotypes
Leptospira interrogans—all serotypes
Listeria—all species
Mima polymorpha
Moraxella—all species
Mycobacteria—all species except those listed in Class 3
Mycoplasma—all species except *Mycoplasma mycoides* and *Mycoplasma agalactiae*, which are in Class 5
Neisseria gonorrhoeae, *N. meningitidis*
Pasteurella—all species except those listed in Class 3
Salmonella—all species and all serotypes
Shigella—all species and all serotypes
Sphaerophorus necrophorus
Staphylococcus aureus
Streptobacillus moniliformis
Streptococcus pyogenes
Treponema caraleum, *T. pallidum*, and *T. pertenue*
Vibrio fetus, *V. comma*, including biotype El Tor, and *V. parahemolyticus*

2. Fungal Agents

¹*Actinomyces* (including *Nocardia* species and *Actinomyces* species and *Arachnia propionica*)
Blastomyces dermatitidis
Cryptococcus neoformans
Paracoccidioides brasiliensis

3. Parasitic Agents

Endamoeba histolytica
Leishmania sp.
Waegleria gruberi
Toxoplasma gondii
Toxocara canis
Trichinella spiralis
Trypanosoma cruzi

4. Viral, Rickettsial, and Chlamydial Agents

Adenoviruses—human—all types
Cache Valley virus

¹Since the publication of the classification in 1974 [1], the *Actinomyces* have been reclassified as bacterial rather than fungal agents.

Corsackie A and B viruses
Cytomegaloviruses
Echoviruses—all types
Encephalomyocarditis virus (EMC)
Flanders virus
Hart Park virus
Hepatitis-associated antigen material
Herpes viruses—except *Herpesvirus simiae* (Monkey B virus) which is in Class 4
Corona viruses
Influenza viruses—all types except A/PR8/34, which is in Class 1
Langat virus
Lymphogranuloma venereum agent
Measles virus
Mumps virus
Parainfluenza virus—all types except *Parainfluenza virus 3, SF4 strain*, which is in Class 1
Polioviruses—all types, wild and attenuated
Poxviruses—all types except *Alastrim*, *Smallpox*, *Monkey pox*, and *Whitepox*, which depending on experiments, are in Class 3 or Class 4
Rabies virus—all strains except *Rabies street virus*, which should be classified in Class 3 when inoculated into carnivores
Reoviruses—all types
Respiratory syncytial virus
Rhinoviruses—all types
Rubella virus
Simian viruses—all types except *Herpesvirus simiae* (Monkey B virus) and *Marburg virus*, which are in Class 4
Sindbis virus
Tensaw virus
Turlock virus
Vaccinia virus
Varicella virus
Vole rickettsia
Yellow fever virus, 17D vaccine strain

C. Class 3 Agents

1. *Bacterial Agents*
*Actinobacillus mallei*²
Bartonella—all species
Brucella—all species
Francisella tularensis
Mycobacterium avium, *M. bovis*, *M. tuberculosis*
Pasteurella multocida type B ("buffalo" and other foreign virulent strains²)
*Pseudomonas pseudomallei*²
Yersenia pestis
2. *Fungal Agents*
Coccidioides immitis
Histoplasma capsulatum
Histoplasma capsulatum var. *duboisii*
3. *Parasitic Agents*
Schistosoma mansoni
4. *Viral, Rickettsial, and Chlamydial Agents*
Alastrim, *Smallpox*, *Monkey pox*, and *Whitepox*, when used *in vitro*
Arboviruses—all strains except those in Class 2 and 4 (*Arboviruses* indigenous to the United States are in Class 3, except those listed in Class 2. *West Nile* and *Semliki Forest* viruses may be classified up or down, depending on the conditions of use and geographical location of the laboratory.)

²USDA permit also required for import or interstate transport.

Dengue virus, when used for transmission or animal inoculation experiments

Lymphocytic choriomeningitis virus (LCM)
Psittacosis-Ornithosis-Trachoma group of agents

Rabies street virus, when used in inoculations of carnivores (See Class 2)

Rickettsia—all species except *Vole rickettsia* when used for transmission or animal inoculation experiments

*Vesicular stomatitis virus*²
Yellow fever virus—wild, when used *in vitro*

D. Class 4 Agents

1. *Bacterial Agents*
None
2. *Fungal Agents*
None
3. *Parasitic Agents*
None
4. *Viral, Rickettsial, and Chlamydial Agents*
Alastrim, *Smallpox*, *Monkey pox*, and *Whitepox*, when used for transmission or animal inoculation experiments
Hemorrhagic fever agents, including *Cri-mean hemorrhagic fever* (Congo), *Junin*, and *Machupo* viruses, and others as yet undefined
Herpesvirus simiae (Monkey B virus)
Lassa virus
Marburg virus
Tick-borne encephalitis virus complex, including *Russian spring-summer encephalitis*, *Kyasanur forest disease*, *Omsk hemorrhagic fever*, and *Central European encephalitis viruses*
Venezuelan equine encephalitis virus, epidemic strains, when used for transmission or animal inoculation experiments
Yellow fever virus—wild, when used for transmission or animal inoculation experiments

II. Classification of Oncogenic Viruses on the Basis of Potential Hazard (2)

A. Low-Risk Oncogenic Viruses

Rous Sarcoma	Rat Leukemia
SV-40	Hamster Leukemia
CELO	Bovine Leukemia
Ad7-SV40	Dog Sarcoma
Polyoma	Mason-Pfizer
Bovine papilloma	Monkey Virus
Rat mammary tumor	Marek's
Avian Leukosis	Guinea Pig Herpes
Murine Leukemia	Lucké (Frog)
Murine Sarcoma	Adenovirus
Mouse mammary tumor	Shope Fibroma
	Shope Papilloma

B. Moderate-Risk Oncogenic Viruses

Ad2-SV40	GaLV
FeLV	HV ateles
HV Saimiri	Yaba
EBV	FeSV
SSV-1	

III. Animal Pathogens (3)

A. *Animal disease organisms which are forbidden entry into the United States by Law (CDC Class 5 agent)*

1. *Foot and mouth disease virus*

B. *Animal disease organisms and vectors which are forbidden entry into the United States by USDA Policy (CDC Class 5 Agents)*

African horse sickness virus
African swine fever virus
Besnoitia besnoiti
Borna disease virus
Bovine infectious petechial fever
Camel pox virus
Ephemeral fever virus
Fowl plague virus
Goat pox virus
Hog cholera virus
Louping ill virus
Lumpy skin disease virus
Nairobi sheep disease virus
Newcastle disease virus (Asiatic strains)
Mycoplasma mycoides (contagious bovine pleuropneumonia)
Mycoplasma agalactiae (contagious agalactia of sheep)
Rickettsia ruminantium (heart water)
Rift valley fever virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Teschen disease virus
Trypanosoma vivax (Nagana)
Trypanosoma evansi
Theileria parva (East Coast fever)
Theileria annulata
Theileria lawrencei
Theileria bovis
Theileria hirci
Vesicular exantema virus
Wesselsbron disease virus
Zyoonema farciminosum (pseudofarcy)

REFERENCES

1. *Classification of Etiologic Agents on the Basis of Hazard*. (4th Edition, July 1974). U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, Office of Biosafety, Atlanta, Georgia 30333.
2. *National Cancer Institute Safety Standards for Research Involving Oncogenic Viruses* (October 1974). U.S. Department of Health, Education, and Welfare Publication No. (NIH) 75-790.
3. U.S. Department of Agriculture, Animal and Plant Health Inspection Service.

Dated: December 15, 1978.

DONALD S. FREDRICKSON,
Director,
National Institutes of Health.

Approved: December 15, 1978.

JULIUS B. RICHMOND,
Assistant Secretary for Health.

Approved: December 15, 1978.

JOSEPH A. CALIFANO, Jr.,
Secretary.

[FR Doc. 78-35533 Filed 12-21-78; 8:45 am]

FRIDAY, DECEMBER 22, 1978

PART VIII



**DEPARTMENT OF
HEALTH,
EDUCATION, AND
WELFARE**

**Food and Drug
Administration**

RECOMBINANT DNA

Intent to Propose Regulations

Registered for

[4110-03-M]

**DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE**

Food and Drug Administration

[21 CFR Part 59]

[Docket No. 78N-0012]

RECOMBINANT DNA**Intent to Propose Regulations**

AGENCY: Food and Drug Administration.

ACTION: Notice of Intent to Propose Regulations.

SUMMARY: The Food and Drug Administration (FDA) intends to propose regulations to require assurances in future submissions to the agency that any recombinant deoxyribonucleic acid (DNA) work that has been or will be performed in connection with these submissions fully complies with the National Institutes of Health (NIH) Guidelines for Recombinant DNA Research. This notice is being issued because the Commissioner of Food and Drugs believes it would be helpful to invite public comment on whether such action would be appropriate and desirable.

DATE: Comments by February 20, 1979.

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

FOR FURTHER INFORMATION CONTACT:

Irvin M. Asher, Office of Health Affairs (HFY-313), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4490.

SUPPLEMENTARY INFORMATION: "Recombinant DNA" molecules have been defined as either (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of such molecules. (See the FEDERAL REGISTER of July 28, 1978 (43 FR 33042, at 33069).) The Food and Drug Administration has received inquiries from pharmaceutical manufacturers and others concerning the use of recombinant DNA techniques in research on, and development and manufacture of, products subject to FDA's jurisdiction.

The Secretary of Health, Education, and Welfare (HEW) has recognized that newly developed techniques for creating and manipulating such molecules constitute scientific tools with unusual promise of bringing about a

better understanding and improved treatment of human disease. As scientists in the field were the first to recognize, however, the new techniques pose potential hazards. Should foreign DNA alter microorganisms in unpredictable, undesirable ways, and should those organisms escape from controlled settings, they could conceivably harm individuals and the environment.

On June 23, 1976, NIH issued comprehensive guidelines setting forth appropriate precautions for work with various types of recombinant DNA molecules (see the FEDERAL REGISTER of July 7, 1976 (41 FR 27902)). All Federal agencies that conduct or sponsor research involving recombinant DNA subsequently endorsed the NIH guidelines. At the time the 1976 guidelines were issued, the Director of NIH emphasized that the guidelines were to remain flexible and subject to continuing review as new information relating to potential risks or safety aspects of the research program was developed (see the July 7, 1976 FEDERAL REGISTER at 41 FR 27905).

Since the publication of the 1976 guidelines, the issues surrounding recombinant DNA research have been widely discussed in congressional hearing, public hearings conducted by NIH, and in scientific journals. Proposed revisions of the guidelines were recommended to the NIH Director by the NIH Recombinant DNA Advisory Committee and were published for public comment in the FEDERAL REGISTER, of September 27, 1977 (42 FR 49596). After an extensive evaluation of the September 27 proposal and the comments received in response to that proposal, the NIH Director issued proposed revised guidelines on July 28, 1978 (43 FR 33042). The comments received in response to the July 28 proposal were reviewed by a Departmental review committee established by the Secretary of HEW. That committee's review of the comments, and the new guidelines, are being published in the FEDERAL REGISTER today.

The Commissioner believes that the new NIH guidelines reflect the best available information on recombinant DNA research and constitute the most workable available guide to responsible practice in this developing area of science. They represent the most sophisticated attempt to date to harmonize freedom for scientific inquiry with protection of the public health and environment with respect to this research. The NIH guidelines have been subjected to scientific and public review and will continue to be updated as new information becomes available.

Therefore, the Commissioner intends to propose regulations to require that any firm seeking approval of a product requiring the use of recombinant

DNA methods in its development or manufacture demonstrate the firm's compliance with the requirements of the NIH guidelines (in effect at the time work involving recombinant DNA is commenced) in connection with any work it has done or will do relating to that product. Such assurance would be required, for example, in notices of claimed investigational exemption of a new drug (IND's), new drug applications (NDA's), license applications for biologic products, requests for certification for antibiotics, feed additive petitions, food additive petitions, and new animal drug applications (NADA's). Further, the Commissioner intends to propose that the NIH guidelines be incorporated in good manufacturing practice regulations, should recombinant DNA techniques be proposed for the manufacture of products for commercial distribution. Although the details for assuring compliance with the NIH guidelines have not yet been worked out, the Commissioner is considering a requirement that all recombinant DNA research being conducted for submission to FDA be registered with FDA. In evaluating such research, FDA would utilize the expertise of NIH as necessary, and might refer specific protocols to NIH for review as to their compliance with the NIH guidelines.

The Commissioner is aware that product-related research involving recombinant DNA is in many cases regarded as commercially sensitive, and is treated as confidential by persons who conduct or sponsor such research. FDA's public information regulations broadly protect trade secret and commercial information that is privileged or confidential (see 21 CFR 20.61). The regulations (21 CFR 20.82(b)) expressly provide that information within the scope of § 20.61 may not be disclosed.

Moreover, specified types of confidential information are prohibited from disclosure by statute. Section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)) prohibits the disclosure, other than to Department employees and to the courts, of any information acquired under authority of specified sections of the act "concerning any method or process which as a trade secret is entitled to protection." The general Federal confidentiality statute, 18 U.S.C. 1905, prohibits the disclosure "in any manner or to any extent not authorized by law" of any information acquired in the course of official duty concerning, among other things, "trade secrets, processes, operation, style of work, or apparatus" of any person (18 U.S.C. 1905).

The regulations to be proposed would provide protections against public disclosure of information con-

cerning the use of recombinant DNA submitted to FDA. In many cases, such information would fall within the protection of section 301(j) of the act as information obtained under FDA's authority regarding research on, or the premarketing approval of, regulated products. Other information would be prohibited from disclosure under 18 U.S.C. 1905. In either circumstance, FDA's regulations proscribe public disclosure of the information, as they do of all information within 5 U.S.C. 552(b)(4). (See 21 CFR 20.61.)

Disclosure of information concerning recombinant DNA to NIH, or to the Recombinant Advisory Committee (RAC), would not affect its status under FDA regulations. The regulations (21 CFR 20.85) provide that information otherwise exempt may be disclosed to "other Federal government departments and agencies" under a suitable agreement restricting further disclosure. Disclosure of this type does not require disclosure to any other person (21 CFR 20.86(b)). Moreover, disclosure to NIH of information within section 301(j) of the act is not inconsistent with that statute, which requires only that information not be released outside HEW.

The Commissioner notes that a technical amendment to § 20.84 of the public information regulations may be

required to make clear that exempt information obtained from FDA may be disclosed by NIH to RAC. Any such amendment would restrict such further disclosure to RAC, whose members are retained by NIH as special government employees.

The Commissioner invites public comment on (1) the authority and role of FDA with regard to the use of recombinant DNA techniques to develop and manufacture products that are under its jurisdiction, and (2) whether existing protections for proprietary information are adequate with respect to information that may be submitted to the agency concerning recombinant DNA research.

The Commissioner also invites comments on the following:

1. Are the measures described above the most appropriate? Will they afford the public adequate protection without undue interference in scientific research and product development? What impact would this regulatory approach have on the development of recombinant DNA techniques for commercial production?

2. Are the NIH guidelines suited to an industrial setting or do they need to be revised and, if so, in what respects? For example, is there interest in using a host-vector system other than *E. coli* K-12, which is already ap-

proved under the NIH guidelines?

3. Which of the procedural requirements of the NIH Guidelines are inappropriate for an industrial setting? In what way should they be revised?

4. Would any special policies with respect to compliance with, and enforcement of, the contemplated regulations be required?

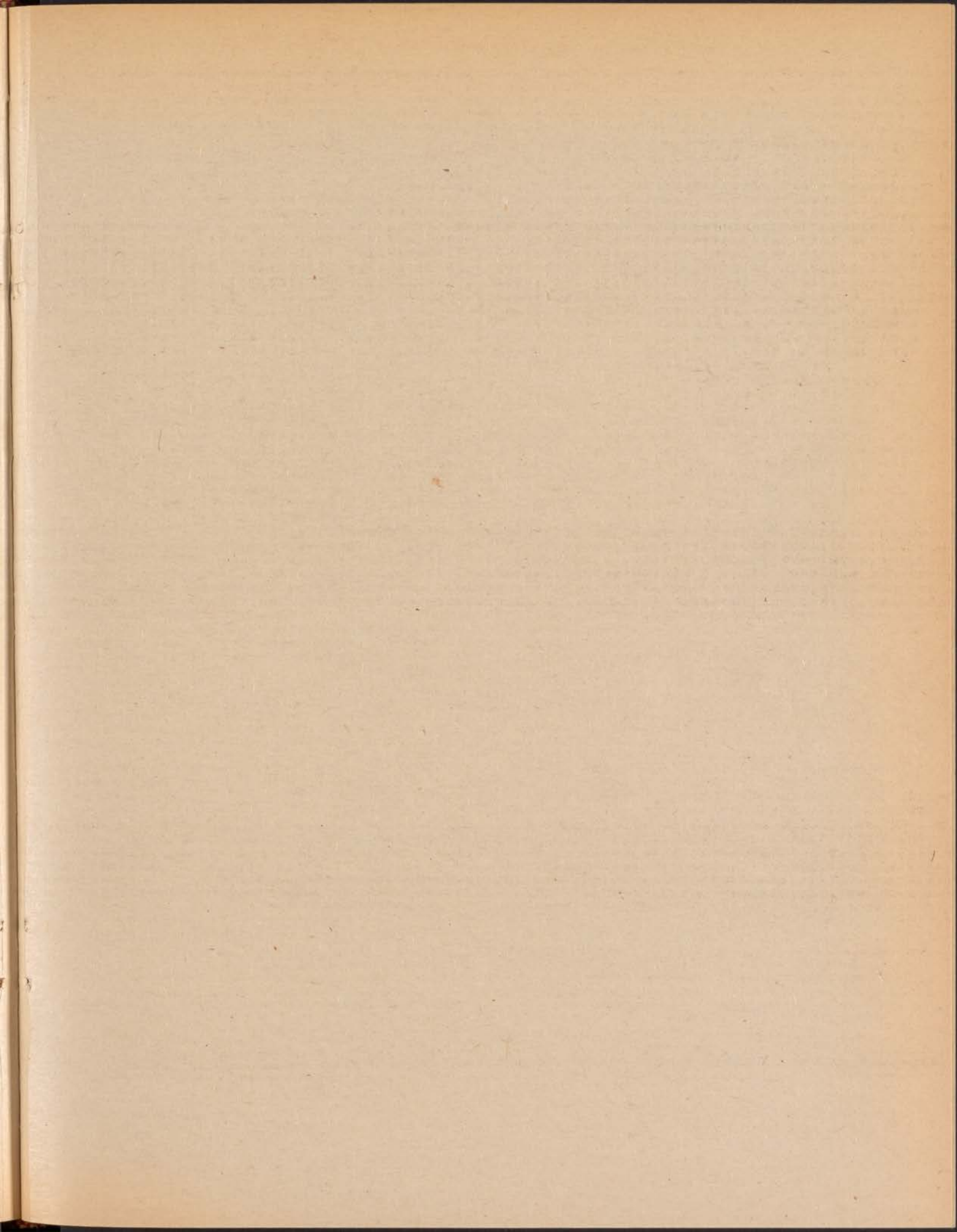
Comments are invited not only on these questions but on any other questions raised by the contemplated action.

Interested persons may, on or before February 20, 1979, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this notice of intent. Four copies of all comments should be submitted, except that individuals may submit single copies of comments. Comments should be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 13, 1978.

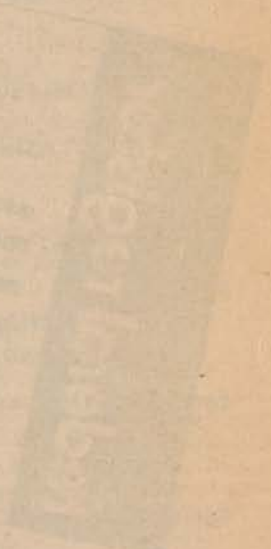
DONALD KENNEDY,
Commissioner of Food and Drugs.

[FR Doc. 78-35534 Filed 12-21-78; 8:45 am]



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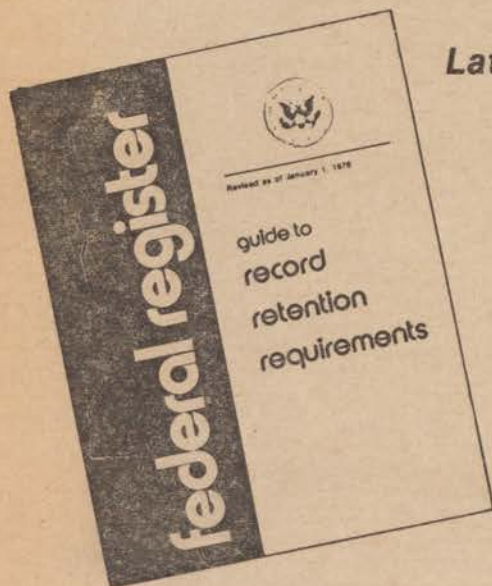


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